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1 THE VIDEOGRAPHER: We are now on the record.
2 My name is Ben Stanson representing Veritext. The
3 date today is March 15, 2019, and the time is
4 9:28 a.m. This deposition is being held at Reed
5 Smith located at 10 South Wacker Drive in Chicago,
6 Illinois and is being taken by counsel for the
7 defendants. The caption of this case is the
8 National Prescription Opiate Litigation pending in
9 the U.S. District Court, Northern District of Ohio,
10 Eastern Division, MDL No. 2804.

11 The name of the witness is Demetra Ashley.
12 Appearances will be noted on the stenographic
13 record. Our court reporter is Gina Luordo
14 representing Veritext. Will you please swear in
15 the witness.

16 (Whereupon, the witness was
17 sworn.)

18 DEMETRA ASHLEY,
19 having been first duly sworn, was examined and
20 testified as follows:

21 EXAMINATION

22 BY MR. NICHOLAS:

23 Q. Good morning, Ms. Ashley.

24 A. Good morning.

25 Q. My name is Bob Nicholas. I represent

1 AmerisourceBergen. Several people will be asking
2 you questions today in this deposition. I'm the
3 first person who's going to be questioning you, and
4 so I just want you to know that I'm not the only
5 one who is going to be questioning you.

6 Do you understand that the Department of
7 Justice has authorized you to testify on certain
8 topics related to your work at the DEA?

9 A. Yes.

10 Q. I'm going to show you the authorization
11 letter that the DEA issued just to know whether
12 you've seen the letter before.

13 MR. NICHOLAS: Can we mark this as Ashley 1,
14 please.

15 (Whereupon, ASHLEY Deposition
16 Exhibit No. 1 was marked for
17 identification.)

18 THE WITNESS: Yes, I've seen it.

19 BY MR. NICHOLAS:

20 Q. Thank you.

21 Did you review the letter in preparation
22 for today's testimony?

23 A. Yes.

24 Q. Have you ever testified at a deposition
25 before?

1 A. Yes.

2 Q. When was that?

3 A. It was internal to DEA. I don't remember
4 the year. I don't recall.

5 Q. Like more than 10 years ago or --

6 A. Probably, yes.

7 Q. Okay. Have you ever testified in a trial
8 before?

9 A. Yes.

10 Q. Just very generally, how many?

11 A. Two.

12 Q. Okay. And just in general terms, what
13 were they about?

14 A. One was about a physician and some
15 diversion, and the second one, I believe it was a
16 pharmacy and diversion.

17 Q. Okay. Do you remember where those trials
18 took place?

19 A. Detroit field division.

20 Q. Okay. And was this back before 2004?

21 A. Yes.

22 Q. Have you been retained to act as an expert
23 in this matter?

24 A. Yes.

25 Q. Okay. And who retained you?

1 A. Purdue Pharma.

2 Q. And since you learned that you would be
3 deposed as a fact witness in this case, have you
4 done any substantive expert work in the case?

5 A. No.

6 Q. And since you learned that you will be
7 deposed as a fact witness in this case, have you
8 done any substantive communicating with Purdue?

9 A. No.

10 Q. Tell us what you did to prepare for your
11 testimony today.

12 A. Yesterday I met with attorneys here
13 representing the government, and they just went
14 over what I could speak about and what I couldn't
15 speak about. So we went over this letter.

16 Q. Okay.

17 A. That was it.

18 Q. Are those the only attorneys that you met
19 in connection with preparing for the deposition?

20 A. Yes.

21 Q. This is a standard question in
22 depositions, so I'll ask it. Approximately how
23 many hours did you spend preparing for the
24 deposition yesterday?

25 A. Yesterday I'd say five hours maybe.

1 Q. I'm going to mark as Exhibit 2 -- I want
2 to mark as Exhibit 2 your LinkedIn profile, okay?

3 A. Okay.

4 (Whereupon, ASHLEY Deposition
5 Exhibit No. 2 was marked for
6 identification.)

7 BY MR. NICHOLAS:

8 Q. My only question, I think, on this is is
9 this your LinkedIn profile?

10 A. Yes, it is.

11 Q. And is it accurate to the best of your
12 knowledge?

13 A. Yes.

14 Q. Now, I want to ask you to go back further
15 than this goes because this takes us back to --
16 your profile goes back to 2004 in terms of your
17 employment history, but have you -- you've been
18 working with the DEA before that, right?

19 A. Yes.

20 Q. How long have you been with the DEA? How
21 long were you with the DEA during the course of
22 your career?

23 A. 36 years.

24 Q. Okay. Can you tell us where you started?
25 What was your first job at the DEA?

1 A. I hired on in the Chicago field division
2 in the Chicago office downtown as a student aide,
3 and I was a student aide for -- I don't know. I
4 was in college -- a few years. And then I was a
5 secretary for about a year, maybe a little longer,
6 and I became a diversion investigator in 1987.

7 Q. In Chicago?

8 A. No. My first posted duty -- well,
9 temporary was the Washington field division. My
10 assigned first posted duty was the Detroit field
11 division, and that was in 1988 when I got to
12 Detroit.

13 Q. Okay. How long were you in Detroit?

14 A. Nine years.

15 Q. And tell me what was your title?

16 A. Diversion investigator.

17 Q. What did you do?

18 A. I conducted investigations of civil -- of
19 a civil nature, criminal and administrative. I was
20 a field investigator going into registrants,
21 helping them with compliance and also detecting
22 violations and pursuing those as, you know,
23 whichever category they fell into, civil
24 administrative or criminal.

25 Q. Okay. What was your next job at the DEA?

1 A. Then I moved to the Chicago field
2 division, and I was still a diversion investigator,
3 and that was in 1996. And I was an investigator,
4 and I did the same -- I had the same duties as
5 following up on investigations, ensuring
6 compliance, some training, that sort of thing. And
7 I became a group supervisor in 1998 still in the
8 Chicago division. I managed two diversion groups
9 and one registration group, and I did that from
10 1998 until 2004.

11 Q. You said you managed two diversion groups
12 and one registration?

13 A. Registration, yeah. Those were the
14 technicians that processed the licenses for the
15 Chicago field division.

16 Q. What was involved with managing the
17 diversion group?

18 A. I was overseeing investigations and
19 regulatory, scheduled investigations, engaging with
20 registrants, ensuring compliance and also detecting
21 diversion and violations.

22 Q. And what was your scope? I mean, what was
23 the territory?

24 A. My territory was just the Chicago area,
25 metropolitan area, you know, suburbs as a group

1 supervisor. I'm sorry. I also had the Springfield
2 office in Illinois. So my two groups were one
3 group in the Chicago area and the second group in
4 Springfield, Illinois.

5 Q. Okay. And then your next job at the DEA
6 was what?

7 A. Then I went to Washington, D.C. for
8 headquarters, and that was in 2004. And I was --
9 they call it staff coordinators. I worked in the
10 policy section, and that was helping to draft
11 policy, providing clarification to registrants in
12 the policy liaison section. And from there, I was
13 in the policy section about a year and a half, and
14 then I was promoted to the associate section chief
15 also in headquarters, and that was in the drug and
16 chemical evaluation section.

17 And I was responsible for the
18 regulatory -- all regulatory matters around the
19 country, kind of national -- it was sort of a
20 national -- I guess I would speak with all the
21 groups around the country and sort of get it into
22 one concise sort of, I guess -- I don't know what's
23 the word I'm looking for. Where they are all on
24 the same page sort of thing. So I was like
25 regulatory providing information from headquarters

1 making sure that the -- around the country they
2 were being consistent with what our priorities
3 were.

4 Q. In that -- in that part of the job, were
5 you communicating with people within the DEA around
6 the country?

7 A. Within DEA, yes.

8 Q. I see. Did you deal with quotas during
9 that period of time when you were in the D.C.
10 office? Was that part of your --

11 A. I did not. Not at that time.

12 Q. So I think we're up to 1987 if I'm -- it
13 if I haven't completely lost track.

14 A. We jumped to 2004.

15 Q. Did I say 1987? Sorry about that. Ignore
16 me.

17 You took me all the way to 2004. Tell me
18 what happened in 2004.

19 A. 2004, that's when I was a staff
20 coordinator, and then I think it was 2006 promoted
21 to the associate section chief. So I was in
22 headquarters from '04 to '07.

23 Q. So what I should have said is you've taken
24 us to 2007. In 2007, where did you go next?

25 A. Then I went back to the Chicago field

1 division. I was the diversion program manager, and
2 in that position, I had a five-state area of
3 responsibility. It was Illinois, Indiana, North
4 Dakota, Minnesota and Wisconsin.

5 Q. Okay. Tell me in general terms what your
6 responsibilities were in that position.

7 A. So I was responsible for the investigative
8 groups throughout the division throughout the five
9 states. So in the end -- I think in the beginning,
10 we had about eight groups. By the end, we had 13
11 groups. So it was all matters regulatory,
12 criminal, civil, training, resources, budget, all
13 matters related to the functions of the diversion
14 control section in the Chicago field division.

15 Q. Is it correct that you were closely
16 involved with enforcing suspicious order monitoring
17 requirements of the Controlled Substances Act while
18 in this role?

19 A. Say that again.

20 Q. Sure. Is it correct that you were closely
21 involved with enforcing suspicious order monitor
22 requirements of the Controlled Substances Act while
23 you were in this job?

24 A. I was involved with that, yes.

25 Q. Okay. And were you aware of the DEA's

1 suspicious order monitoring policies during this
2 period of time?

3 A. Yes.

4 MR. SHKOLNIK: Objection to when you say this
5 period of time.

6 BY MR. NICHOLAS:

7 Q. 2007 to 2015 is what I'm talking about.

8 A. Yes.

9 Q. Okay. Now, in 2015, where did you go from
10 there within the DEA?

11 A. In 2015, I went back to headquarters. I
12 was promoted to a senior executive management
13 position. So I went back to the Office of
14 Diversion Control in headquarters in Arlington,
15 Virginia.

16 Q. Okay. And what were your responsibilities
17 in this new senior position?

18 A. So I was responsible for all functions of
19 the Office of Diversion Control. So that would be
20 adequate resources, investigations, training,
21 budget, the growth, the strategy and just
22 coordinating nationally, well, actually globally,
23 to ensure that investigators were on focus with
24 DEA's mission and Office of Diversion strategy.

25 Q. Who did you report to in that role?

1 A. Louis Milione.

2 Q. Did you report to Joseph Rannazzisi for
3 any period of time?

4 A. No, I did not.

5 Q. And during that period of time, were you
6 aware of the DEA's suspicious order monitoring
7 policies?

8 A. Yes.

9 Q. I am going to ask you one question about
10 your LinkedIn page and only one, which is on your
11 LinkedIn page, you said you increased public and
12 industry engagement by more than 500 percent to
13 expand the agency's presence and improve
14 compliance. Can you just explain that? What did
15 you mean?

16 A. So one of the things that Lou and I
17 discussed when we -- we both reported at the same
18 time is that we wanted to have, you know, more
19 training, lots of engagement because we felt
20 that -- well, actually not we felt that. We were
21 told by industry that they weren't engaging with
22 DEA enough. They needed clarification and policy.
23 So we felt that we should do a lot more of that, so
24 that was one of the initiatives we placed out to
25 the field and asked them to, you know, just do more

1 engagement.

2 MR. SHKOLNIK: Once again, my objection is to
3 time frame. Can you just --

4 MR. NICHOLAS: I'm talking about the time
5 period when Ms. Ashley was at -- was in her senior
6 position from roughly 2015 to 2018.

7 MR. SHKOLNIK: I understand. There should be
8 clarity. Objection to form just so it's clear.

9 MR. NICHOLAS: Okay. That's fine.

10 BY MR. NICHOLAS:

11 Q. You said that you and Mr. Milione came in
12 at the same time. Who did each of you replace?

13 A. Joseph Rannazzisi.

14 Q. You both came in to replace Mr. Rannazzisi
15 in combination?

16 A. Yes.

17 Q. And during your time in this role in this
18 senior role when you and Mr. Milione were there,
19 was there a shift in how the DEA worked with its
20 registrants?

21 MR. SHKOLNIK: Objection.

22 BY MR. NICHOLAS:

23 Q. You can go ahead.

24 A. I believe so, yes.

25 MR. SHKOLNIK: Just note my objection. Is the

1 witness speaking on behalf of DEA, or is this a
2 personal opinion? I'm directing that to DEA
3 counsel.

4 MR. NICHOLAS: Let me just -- we're not going
5 to have speaking objections.

6 MR. SHKOLNIK: I'm allowed to make that
7 objection. I'm asking counsel very clearly is the
8 witness testifying as a policy voice for this
9 agency, or is the witness giving an opinion of her
10 own? We were given certain limitations in this
11 deposition as to what we would be allowed to do and
12 what the witness would be allowed to do.

13 MS. BACCHUS: On behalf of the government, the
14 witness is here to testify in her factual capacity.
15 She is not the representative of DEA. She can
16 testify to what her personal knowledge is and what
17 she performed -- duties she performed on behalf of
18 DEA, but she is not here to speak as a 30(b)(6)
19 witness on DEA policy, and that can go forward.

20 That will be our standing objections. If
21 there are any questions asked regarding DEA itself,
22 she can testify to what she did as a fact witness.

23 MR. SHKOLNIK: Thank you.

24 BY MR. NICHOLAS:

25 Q. You just said that you believed you saw a

1 shift in how the DEA worked with registrants. Can
2 you describe what that shift was?

3 A. When we began as -- relatively soon after
4 we reported, we were getting meeting requests from
5 industry, and in those requests, industry
6 individuals would say to us we have not been able
7 to have these meetings and have these discussions.
8 So that's my knowledge.

9 Q. Thank you.

10 Do you know what -- during what period of
11 time Mr. Rannazzisi held the senior position that
12 you and Mr. Milione replaced him for?

13 A. I don't know for certain.

14 Q. Okay. If I said it was from 2007 to 2015,
15 does that sound right?

16 A. For sure he was there at that time.

17 Q. Okay. And during that time, he was a
18 deputy assistant administrator of the Office of
19 Diversion Control --

20 A. That's correct.

21 Q. -- in the DEA? Thank you.

22 Okay. During your time at the DEA, did
23 you become familiar with the regulation relating to
24 identification and reporting of suspicious orders?

25 A. Yes.

1 Q. And would that be -- was that -- is that
2 21 CFR Section 1301.74?

3 A. It's in 1301. I can't speak to which
4 section, but it's in 1301.

5 Q. I'm going to give you the thing so you can
6 look at it.

7 MR. NICHOLAS: Can we mark as Ashley 3, please,
8 the next exhibit.

9 (Whereupon, ASHLEY Deposition
10 Exhibit No. 3 was marked for
11 identification.)

12 BY MR. NICHOLAS:

13 Q. So Ms. Ashley, I've handed you a copy of
14 21 CFR Section 1301.74. Do you recognize it --

15 A. Yes.

16 Q. -- as the regulation?

17 A. Yes.

18 Q. And I'm going to direct you probably most
19 specifically to Section B. Is this section -- does
20 this section pertain to requirements directed to
21 distributors?

22 A. Yes.

23 Q. And distributors are registrants; is that
24 correct?

25 A. Correct.

1 Q. If you look at Section B of this
2 regulation, does the regulation tell registrants,
3 specifically distributors, how to identify
4 suspicious orders?

5 A. I guess my answer would be somewhat, yes.

6 Q. Okay. Is there an element of subjectivity
7 to it?

8 A. Yes.

9 Q. Does the regulation explain how to
10 identify an order of, quote, unusual size?

11 A. How to do it? Yes.

12 Q. Does -- how does it do that?

13 A. When it says to identify orders deviating
14 from -- substantially from a normal pattern, that
15 would make it unusual. That's my opinion.

16 Q. Does the regulation tell -- provide
17 guidance as to what constitutes an order of unusual
18 size?

19 A. No.

20 Q. Does the regulation provide guidance as to
21 what constitutes an order of unusual frequency?

22 A. No.

23 Q. Does the regulation provide guidance as to
24 what constitutes an order that deviates
25 substantially from normal ordering pattern?

1 A. I would have to say in general, yeah, it
2 does.

3 Q. How does it do that?

4 A. By saying it's deviating from the normal
5 pattern.

6 Q. Okay. And does it explain what that
7 means?

8 A. You would need to know what was normal, so
9 I think so.

10 Q. And would normal vary from case to case?

11 A. Yes.

12 Q. And situation to situation?

13 A. Yes.

14 Q. Does the regulation say what type of
15 reports are supposed to be submitted?

16 A. The type?

17 Q. Well, what they're supposed to look like,
18 what's supposed to be in them.

19 A. The regulation does not say that.

20 Q. Does the regulation say anything about
21 whether a registrant can ship an order that it has
22 reported as suspicious?

23 A. It doesn't say if they should ship it. Is
24 that what your question was? Should they tell them
25 whether or not to ship it? Is that what you're

1 asking me?

2 Q. Yeah.

3 A. It does not.

4 Q. Okay. Now, during the time that you were
5 at the DEA, was this regulation ever changed?

6 A. No.

7 Q. To your knowledge, has the regulation ever
8 changed since it was promulgated in 1971?

9 MS. BACCHUS: Objection.

10 BY MR. NICHOLAS:

11 Q. If you know.

12 A. I don't think so.

13 Q. I would like to ask you a few questions
14 about pre-2005 if we can go all the way back then.
15 When you were a diversion investigator prior to
16 2005, do you recall that -- do you recall
17 registrants reporting suspicious orders to the DEA
18 field offices where you worked?

19 A. Yes.

20 Q. And at that time prior to 2005, do you
21 recall that those were called excessive purchase
22 reports?

23 MR. SHKOLNIK: Objection to form.

24 BY MR. NICHOLAS:

25 Q. Go ahead.

1 A. Yes.

2 Q. Do you recall how often those reports were
3 submitted?

4 A. No.

5 Q. Were they submitted on a monthly basis?

6 MR. SHKOLNIK: Objection.

7 THE WITNESS: I don't know. No. I mean, I
8 don't know for sure.

9 BY MR. NICHOLAS:

10 Q. Okay. Do you remember what information
11 those reports contained?

12 A. Somewhat, yes.

13 Q. Can you tell me at all if you remember
14 what was in those reports?

15 A. For the most part, they were line items of
16 transactions made by the distributors' sales and
17 the line items, computer-generated line items.

18 Q. Now, did you have an understanding then as
19 to whether the orders listed on those reports had
20 been shipped?

21 A. For the most part, I recall that they had,
22 yeah.

23 Q. And back then, was that the standard
24 practice in the industry?

25 MR. SHKOLNIK: Objection to form.

1 THE WITNESS: I can't say that that was the
2 standard at the time.

3 BY MR. NICHOLAS:

4 Q. Maybe that's a bad question. Was that --
5 let me try it this way.

6 Was that -- in your personal experience
7 back then, was that typical of what you saw when
8 you got these excessive purchase reports, they were
9 reporting on orders that had been shipped?

10 MR. SHKOLNIK: Objection. Asked and answered.

11 THE WITNESS: I believe so. That's the best I
12 can say.

13 BY MR. NICHOLAS:

14 Q. Okay. Do you know why the registrants,
15 the distributors were submitting this particular
16 type of report?

17 A. Yeah, required by regulation.

18 Q. Okay. And so in other words, what you
19 understood -- am I correct that your understanding
20 is that the distributors were submitting these
21 excessive purchase reports in order to meet their
22 obligations with their suspicious order reporting
23 obligations under 1301.74?

24 MR. SHKOLNIK: Objection.

25 MS. BACCHUS: Objection to form.

1 MR. SHKOLNIK: Form.

2 BY MR. NICHOLAS:

3 Q. You can answer.

4 A. Yes.

5 Q. Thank you.

6 Did you, while working in the field prior
7 to 2005, ever tell any registrant -- when I say
8 registrant, I probably should just say distributor.
9 It will probably be easier right? I'll try to
10 remember to do that.

11 Did you, while working in the field
12 through 2004, ever tell any distributor that these
13 reports were insufficient to comply with the
14 regulation?

15 A. Yes.

16 Q. Who did you tell that to?

17 A. I don't -- I couldn't recall a specific
18 name.

19 Q. Okay. And was that because of a specific
20 instance, a specific circumstance?

21 A. Lots of circumstances. We frequently got
22 excessive order reports and frequently had
23 questions about them because we felt that they were
24 not sufficient to -- we couldn't determine from
25 what they sent in exactly was excessive about it,

1 so we frequently made phone calls to the
2 registrants.

3 Q. Okay. And when you made those, what
4 was -- how did that work itself out? You would
5 call the distributor or the registrant and have a
6 conversation. Then what would happen?

7 MR. SHKOLNIK: Objection. This is --
8 objection. This is going into investigation. We
9 were told this was not allowed.

10 BY MR. NICHOLAS:

11 Q. You can go ahead.

12 A. The gist of the conversations would be we
13 received line items of sales transactions, and it's
14 labeled excessive purchase. So how do we know? I
15 mean, there's nothing identifying that it's
16 actually excessive. So it was more of us trying to
17 get an understanding of what are you sending us.

18 Q. Before 2005, had the DEA, to your
19 knowledge, issued any written policies or
20 guidelines to distributors regarding the suspicious
21 order requirements?

22 MR. SHKOLNIK: Objection. Form.

23 THE WITNESS: I'm not certain.

24 BY MR. NICHOLAS:

25 Q. Go ahead.

1 A. I'm not certain of that.

2 Q. Before 2005, did the DEA have any internal
3 policies providing guidance as to what the DEA was
4 supposed to do with the excessive purchase reports?

5 MS. BACCHUS: Objection to form.

6 THE WITNESS: I don't recall. I was just going
7 to say it was likely.

8 BY MR. NICHOLAS:

9 Q. Okay. All right. I'm going to switch
10 topics and ask you a few questions about the
11 registration of new pharmacies prior to 2005, okay?

12 As a diversion investigator, did you
13 participate in the registration of new pharmacies?

14 MS. BACCHUS: Objection. Scope.

15 BY MR. NICHOLAS:

16 Q. Go ahead.

17 A. No.

18 MR. SHKOLNIK: For the record, we were given
19 specific areas that were allowed to be covered, and
20 plaintiffs relied upon that. We prepared for that.
21 And for the witnesses to be allowed to go outside
22 the scope is really, putting it nicely, unfortunate
23 and I think inappropriate. We would ask the
24 government to please restrict the scope that you
25 limited us to.

1 MS. BACCHUS: If you'd give me an opportunity,
2 I'm objecting on the grounds of scope. She is not
3 authorized to testify today about registrations.
4 If you look at her Touhy authorization, it was not
5 about registrations.

6 MR. NICHOLAS: Well, I think what I'm trying to
7 do here is talk to her about her -- I believe this
8 falls within the scope of her employment history.
9 I want to know if it falls within the scope of her
10 employment history. If it doesn't, it doesn't.

11 MS. BACCHUS: Well, you can ask her if she --
12 she can testify regarding her general employment
13 history, but not as to registration and what she
14 did in regards to that because that's not within
15 the scope of what she is authorized to testify to.
16 She can testify to what her general history was.

17 MR. NICHOLAS: Okay. I promise I'm not going
18 to argue with you about this a whole bunch because
19 time is ticking away. The only thing I'll say is
20 that I believe in her prior testimony here today,
21 Ms. Ashley said that she supervised people who --
22 she supervised people who dealt with the
23 registration of pharmacies. So to the extent that
24 she did that, I would like to be able to ask her
25 about that.

1 MS. BACCHUS: No, that's not within her
2 authorization. A request was not regarding
3 registration and talking about that. If you go
4 back to the Touhy request, that was not part of the
5 request itself.

6 MR. NICHOLAS: Okay. If you're instructing her
7 not to answer, I'm going to move along.

8 MS. BACCHUS: Yes, I am. I am.

9 BY MR. NICHOLAS:

10 Q. Okay. Let's jump to March of 2007. In
11 2007, you returned to Chicago as the -- as a -- as
12 the diversion program manager; is that correct?

13 A. Yes.

14 Q. And in that connection -- in that job, you
15 were responsible for dealing with the diversion
16 program in five states?

17 A. Uh-huh.

18 Q. And around that time, around 2007, did the
19 DEA tell distributors at some point in that time
20 frame that excessive purchase reports would no
21 longer comply with their suspicious order reporting
22 requirements?

23 MS. BACCHUS: Objection to form.

24 MR. SHKOLNIK: Objection to form.

25

1 BY MR. NICHOLAS:

2 Q. You can go ahead.

3 A. I don't recall if that was 2007.

4 Q. Do you recall it happening at some point?

5 A. Your question was not submit excessive
6 purchase reports?

7 Q. Did the DEA tell distributors that they --
8 that excessive purchase reports would no longer
9 serve to meet the requirements under the
10 regulation?

11 MR. SHKOLNIK: Objection to form.

12 MS. BACCHUS: Objection. Form.

13 THE WITNESS: The manner in which they were
14 submitted, DEA did tell registrants in notification
15 to registrants that the manner it had been
16 submitted would change.

17 BY MR. NICHOLAS:

18 Q. Do you remember when that was?

19 A. I thought it was before. Maybe 2006.

20 Q. Okay. And in 2006 or 2007, did the DEA
21 communicate to distributors that they should not
22 ship orders that they reported to the DEA as
23 suspicious?

24 MS. BACCHUS: Objection. Form.

25 THE WITNESS: Should not?

1 BY MR. NICHOLAS:

2 Q. Let me say it again.

3 A. Yes, please.

4 Q. In or around 2006, 2007, did the DEA
5 communicate to distributors that they should not
6 ship orders that they reported to the DEA as
7 suspicious?

8 MS. BACCHUS: Objection to form.

9 MR. SHKOLNIK: Objection. Form.

10 THE WITNESS: I do not recall that.

11 BY MR. NICHOLAS:

12 Q. Do you recall whether at any point the DEA
13 told or instructed distributors that they should no
14 longer ship orders that were reported as
15 suspicious?

16 MR. SHKOLNIK: Objection to form.

17 MS. BACCHUS: Objection. Form.

18 THE WITNESS: I do recall conversations about
19 it, yeah. I won't call it a conversation. A
20 presentation.

21 BY MR. NICHOLAS:

22 Q. A presentation?

23 A. Yeah.

24 Q. Okay. What was the presentation that you
25 recall?

1 A. It was one -- you know what, I don't want
2 to guess. I just remember --

3 Q. Don't guess.

4 Okay. Do you recall that you, yourself
5 were unclear as to this issue of whether
6 distributors should not ship orders that they had
7 reported as suspicious?

8 MR. SHKOLNIK: Objection. Form.

9 THE WITNESS: I never felt unclear. I never
10 felt unclear.

11 MR. NICHOLAS: Can we mark the next exhibit,
12 please.

13 (Whereupon, ASHLEY Deposition
14 Exhibit No. 4 was marked for
15 identification.)

16 BY MR. NICHOLAS:

17 Q. This is an e-mail to Barbara Boockholdt
18 from you dated February 24th of 2010, and it's CC
19 to Delores Williams. Let me just, first of all,
20 ask you who Barbara Boockholdt is. I know she was
21 with the DEA at this time.

22 A. Barbara Boockholdt is a diversion
23 investigator. At the time she was a section chief
24 in the regulatory section in headquarters.

25 Q. And who is Delores Williams?

1 A. Delores Williams was a group supervisor in
2 the Merrillville office under the Chicago field
3 division.

4 Q. So when you wrote this e-mail in 2010, you
5 were in Chicago, correct?

6 A. Yes.

7 Q. So at that time you were the diversion
8 program manager for five states, right?

9 A. Yes.

10 Q. I'm going to direct your attention to the
11 second paragraph, and I'll read it out loud for the
12 record. You write to Barbara Boockholdt about
13 Kroger's submission of an excessive movement
14 report. Your second paragraph reads as follows:
15 My second concern is the sentence, quote, when the
16 registrant reports a customer whose order they
17 determine to be suspicious, that the customer's
18 order cannot be fulfilled, unquote, are you asking
19 that the field contact registrants and tell the
20 registrant that they cannot fill an order based
21 solely on our review of a suspicious order report,
22 question mark, question mark. On what authority do
23 we have to tell a registrant that they cannot fill
24 an order absent an investigation and clear
25 violations?

1 Having read that, do you recall now that
2 at this point in time, you were not clear as to
3 whether there was authority to tell distributors
4 that they could not ship suspicious orders?

5 MR. SHKOLNIK: Objection. Form.

6 BY MR. NICHOLAS:

7 Q. Go ahead.

8 A. Well, actually, at that time I was
9 fielding -- I was sort of pulling Barbara out of
10 it. It was more to the contrary. I've always felt
11 in my time as a diversion investigator that it is
12 an expectation that a registrant wouldn't ship an
13 order that they identified as suspicious. It's
14 the -- ultimately the registrant's decision to
15 ship, so it's not DEA's. That's my -- in my
16 practice as a diversion investigator to instruct a
17 registrant, it's the registrant's discretion
18 whether or not they're going to ship. It is the
19 expectation that if they identify it as suspicious
20 that they wouldn't, but they have to make the call.

21 Q. So it correct that in your view, it was an
22 expectation, but not a requirement?

23 MR. SHKOLNIK: Objection to form. Misstating
24 the witness's testimony.

25 MR. NICHOLAS: Well, she can tell me whether

1 it's correct or incorrect.

2 THE WITNESS: Expectation and not a
3 requirement? No. The requirement was that they
4 make the decision.

5 BY MR. NICHOLAS:

6 Q. Okay.

7 A. That was the requirement.

8 Q. Okay. Prior to 2007, did the DEA work
9 with distributors to review and approve suspicious
10 order monitoring programs?

11 MS. BACCHUS: Objection to form.

12 BY MR. NICHOLAS:

13 Q. Prior to 2007.

14 A. Prior to 2007, I was in headquarters. Did
15 they work with registrants?

16 Q. Yeah.

17 A. I don't know if I can speak on behalf of
18 the agency. I can say that I did.

19 Q. You did?

20 A. Yeah.

21 Q. Okay. Was there a point in time when the
22 DEA adopted a policy, if you want to call it that,
23 of ceasing to approve or endorse any specific
24 system for suspicious order reporting systems?

25 MS. BACCHUS: Objection to form.

1 THE WITNESS: So we never did approve them or
2 endorse the systems. What we did was have
3 discussions with the registrants and sort of just
4 discussed with them if their system was effective,
5 but we never approved.

6 BY MR. NICHOLAS:

7 Q. Are you aware of whether the DEA approved
8 AmerisourceBergen's system in the late '90s system
9 of reporting?

10 A. I'm not aware.

11 Q. Now, when you say that the DEA never
12 endorsed or approved any system, did the DEA work
13 with registrants in connection with their systems?

14 MS. BACCHUS: Objection to form.

15 BY MR. NICHOLAS:

16 Q. I should say did you. Did you?

17 A. Did I? Yes. I mean, you know, you go to
18 a registrant's location, and they show you what
19 their system is, and you have a discussion about
20 whether or not it's effective or if you feel that
21 it's effective. You may make some suggestions that
22 would help them, you know, just to ensure
23 compliance, but there was never, you know, I
24 approve the system. It's just a discussion.

25 Q. Did those sorts of discussions cease

1 sometime after 2007?

2 A. Me personally, no.

3 Q. You continued to work with distributors
4 and registrants?

5 A. After 2003?

6 Q. Yes.

7 A. I'm trying to think where was I.

8 Q. You were in Chicago.

9 A. I was in Chicago. No, I always had those
10 discussions.

11 Q. Okay. I'm going to dig out a document.
12 Just give me a second.

13 MR. NICHOLAS: Can we go off the record just so
14 I can ask one question.

15 THE VIDEOGRAPHER: We're off the record at
16 10:13 a.m.

17 (Whereupon, a discussion was
18 had off the record.)

19 THE VIDEOGRAPHER: We are back on the record at
20 10:14 a.m.

21 MR. NICHOLAS: I'd like to mark this as the
22 next exhibit in this deposition, and I confess I
23 have forgotten the number. Is it No. 4? 5.
24 Ashley 5.

25

1 (Whereupon, ASHLEY Deposition
2 Exhibit No. 5 was marked for
3 identification.)

4 BY MR. NICHOLAS:

5 Q. What I've marked is a copy of a letter
6 dated December 27, 2007 over the signature of
7 Joseph T. Rannazzisi, deputy assistant
8 administrator, Office of Diversion Control. It
9 begins dear registrant, and then there's text.
10 Have you seen this letter before?

11 A. Yes.

12 Q. Okay. How would you describe -- what's
13 the letter? What is it?

14 A. It's -- it goes to the registrant. It
15 provides just sort of guidance to registrants on
16 how they should report, when they should report
17 suspicious orders.

18 Q. Was this a requirement, or was it -- were
19 these requirements, or was this guidance?

20 MS. BACCHUS: Objection. Form.

21 THE WITNESS: It says requires.

22 BY MR. NICHOLAS:

23 Q. Okay. I'd like to direct you to the
24 second paragraph, the middle of the paragraph where
25 the -- and I'll read from the middle of the

1 paragraph to the end if that's okay.

2 A. Okay.

3 Q. The regulation clearly indicates that it
4 is the sole responsibility of the registrant to
5 design and operate such a system. Accordingly, DEA
6 does not approve or otherwise endorse any specific
7 system for reporting suspicious orders. Past
8 communications with DEA, whether implicit or
9 explicit, that could be construed as approval of a
10 particular system for reporting suspicious orders
11 should no longer be taken to mean that DEA approves
12 a specific system.

13 Do you see that?

14 A. Yeah.

15 Q. Okay. Now that you've read this, does it
16 refresh your memory as to whether prior to this
17 letter there were instances where the DEA did give
18 its approval of a particular system?

19 MR. SHKOLNIK: Objection to form.

20 MS. BACCHUS: Objection to form.

21 BY MR. NICHOLAS:

22 Q. I'm just asking.

23 A. I was not aware after even reading this
24 the DEA ever approved systems for order. Not in my
25 experience.

1 Q. During your tenure in the Office of
2 Diversion --

3 MR. NICHOLAS: Can somebody go back on mute,
4 please. Thank you.

5 BY MR. NICHOLAS:

6 Q. Next topic. During your tenure in the
7 Office of Diversion Control, did you believe it was
8 important to communicate with distributors?

9 A. Yes.

10 Q. And does that include -- does that
11 communication -- strike that.

12 And does that include communicating with
13 distributors to make sure that they understand what
14 the DEA's expectations are?

15 A. Yes.

16 Q. Are you aware that the DEA has been
17 criticized for its failure to communicate with the
18 distributor community?

19 A. Yes.

20 Q. And are you aware that members of Congress
21 have openly criticized the DEA's lack of
22 communication with the registrant distributor
23 community in relation to the opioid epidemic?

24 MR. SHKOLNIK: Objection. Form.

25 THE WITNESS: The tail end, the end relations

1 of the opioid epidemic, but the beginning -- the
2 criticism, I'm aware of that.

3 BY MR. NICHOLAS:

4 Q. When you became the deputy assistant
5 administrator at DEA headquarters in 2015, was part
6 of your mission to improve that relationship
7 between the DEA and the distributors?

8 A. Yes.

9 Q. Now, we've mentioned Lou -- is it Milione
10 or --

11 A. Milione.

12 Q. You pronounce the E?

13 A. Yeah, he does.

14 Q. We've mentioned him, but who is
15 Mr. Milione, and what was his role at the DEA as of
16 January 2016?

17 A. January 2016 Lou Milione was the assistant
18 administrator for the diversion control division.

19 MR. NICHOLAS: I'd like to mark the next
20 exhibit, please, as Ashley 6.

21 (Whereupon, ASHLEY Deposition
22 Exhibit No. 6 was marked for
23 identification.)

24 BY MR. NICHOLAS:

25 Q. So what I've handed you are really two

1 documents. The first is a covering e-mail from
2 Matthew Strait at the DEA to Mr. Milione with CC to
3 Gary Owen and Christopher Scheuler, and the
4 attachment is something headed DEA Communication
5 With Registrants. The attachment is dated
6 September 29, 2015. The covering e-mail is dated
7 January 8, 2016. I just have a few questions about
8 this.

9 You can see in this e-mail chain that
10 Mr. Strait is sending the attachment to
11 Mr. Milione, and he says Lou, as -- Mr. Milione's
12 first name is Lou?

13 A. Yes.

14 Q. As discussed here are the TP, which I'm
15 going to speculate is talking points?

16 A. Correct.

17 Q. Documents that we prepared for Jack's last
18 hearing that pertain to the issues that may be
19 raised during the January 27th hearing.

20 Do you see that?

21 A. Yes.

22 Q. So it looks like Mr. Milione was about to
23 testify somewhere, and he was being provided with
24 documents, you know, talking points, correct?

25 A. Yes.

1 MS. BACCHUS: Objection.

2 BY MR. NICHOLAS:

3 Q. Let's look at the talking points. So in
4 the talking points provided to Mr. Milione, there's
5 a question posed, and the question is I have heard
6 many complaints from manufacturers and distributors
7 that DEA continually fails to adequately
8 communicate with them. Would you agree with me
9 that DEA has fallen short in its communications --
10 in its communication responsibilities with
11 registrants and that DEA can do better in serving
12 those with whom they regulate?

13 Do you see that?

14 A. Yes.

15 Q. And then the first part of the talking
16 point, proposed talking point response was we've
17 heard from various members of Congress regarding
18 this issue, and Acting Administrator Rosenberg and
19 I have made some important changes within the
20 Office of Diversion Control, the program office
21 that has direct regulatory oversight of our
22 1.6 million registrants.

23 So I guess my question to you is what were
24 the important changes within the Office of
25 Diversion Control that's being referred to in these

1 talking points, if you know?

2 A. So at the time I was there in headquarters
3 working for Lou, and the changes were that we were
4 accepting meetings in the headquarters office from
5 registrants. We gave a directive out to the field
6 to increase their engagement. We turned back on a
7 few initiatives that had been turned off. Well, I
8 don't want to say that had been turned off. They
9 weren't given as much attention, I'd say that, and
10 engagement with registrants.

11 Q. Under Mr. Rannazzisi's tenure, was he not
12 accepting meetings at headquarters with
13 distributors?

14 MS. BACCHUS: Objection.

15 THE WITNESS: I don't exactly know. I wasn't
16 there. I can tell you those are complaints we got.
17 BY MR. NICHOLAS:

18 Q. And when you say that you either turned
19 back on or gave more much more priority to some
20 initiatives, were those initiatives ones that had
21 been either turned off or deprioritized by under
22 the prior regime?

23 MR. SHKOLNIK: Objection to form.

24 MS. BACCHUS: Objection.

25 MR. SHKOLNIK: Misstates testimony.

1 MR. NICHOLAS: I'm asking. I'm not stating
2 anything.

3 BY MR. NICHOLAS:

4 Q. Go ahead.

5 A. I don't want to say that he deprioritized
6 it, but there were -- I'll just give you an
7 example. There were meetings that registrants
8 would request, and they weren't -- they weren't
9 happening as often, and so we just directed our
10 liaison of policy section to accept the meetings.
11 So it just made it a priority.

12 Q. Did you see a change?

13 A. Yes.

14 Q. Do you recall giving a presentation in
15 October of 2016 to NASCSA?

16 A. National Association of Chain Pharmacies
17 and Distributors?

18 Q. I'm not sure that's what the acronym
19 stands for. Hold on one second.

20 MR. MAHADY: National Association of State
21 Controlled Substance Authorities?

22 THE WITNESS: I don't recall. I don't recall.

23 BY MR. NICHOLAS:

24 Q. Do you recall giving a presentation in New
25 Orleans?

1 A. Yes.

2 Q. Okay. I think that's the one we're
3 talking about.

4 A. That helps, yes.

5 Q. If I say it was in October of 2016, does
6 that sound about right?

7 A. Probably.

8 Q. And it was to this group, this NASCSA
9 group?

10 A. Yeah.

11 MR. NICHOLAS: Let's mark as the next exhibit,
12 please, as Exhibit 7, Ashley 7 this next document.

13 (Whereupon, ASHLEY Deposition
14 Exhibit No. 7 was marked for
15 identification.)

16 MR. SHKOLNIK: I want to note an objection.
17 Late last night Purdue Pharma turned over or
18 produced for the first time a PowerPoint
19 presentation for October 2016, and I can only
20 assume this is the document you're going into next.
21 It's not? Well, we'll bring that issue up later at
22 a break.

23 MR. NICHOLAS: Okay.

24 MS. BACCHUS: We haven't gotten the document.

25 MR. NICHOLAS: I'm sorry.

1 BY MR. NICHOLAS:

2 Q. Now, Ms. Ashley, what I've given you is a
3 document, I believe, was produced in this
4 litigation by Purdue in which there's a series of
5 e-mails, but the one -- I'm not interested in the
6 e-mails that talk about the dinner plans and how
7 much the person loves New Orleans restaurants and
8 stuff like that. I'm only interested in the one
9 from David Haddox to Kathleen Konka dated
10 October 19, 2016, and it's regarding -- the subject
11 is Re DEA update from NASCSA meeting.

12 And I apologize. That's not even the
13 e-mail I want you to read. Let's start that again.
14 Go back further. What I want you to take a look
15 at, the only thing I need you to look at is -- it's
16 from David Haddox to group, a bunch of people. I'm
17 not sure --

18 MR. SHKOLNIK: Can you tell us the time?

19 MR. NICHOLAS: Yes. This one is from David
20 Haddox. It's dated October 19, 2016 at 4:56 p.m.

21 BY MR. NICHOLAS:

22 Q. The subject is DEA update from NASCSA
23 meeting. And the only reason I'm showing this to
24 you is because I want to remind you, perhaps, of
25 what you said in the meeting.

1 A. Okay.

2 Q. This summarizes what you said in the
3 meeting. You can tell me whether it's accurate or
4 not. The writer, Mr. Haddox says this morning I
5 attended a presentation by Demetra Ashley,
6 associate deputy assistant administrator, DEA.
7 Some interesting information. And I'm going to
8 direct you -- I'm going to direct you actually to
9 No. 4.

10 No. 4 reads -- he has numbered
11 paragraphs 1, 2, 3, 4, 5, 6 and so forth. And
12 No. 4 reads distributor initiative, slide 16, A,
13 this is a program started in 2005 put on hold and
14 restarting now.

15 Do you remember -- what do you remember
16 about this, about the distributor initiative?

17 A. Again, that it started in 2005. I
18 remember that it's an opportunity to speak with
19 distributors and to show them their information
20 that they report to our folks and have an informal
21 dialogue on how DEA views their transactions and
22 have a discussion with them about how they view it.
23 We have a discussion about the global issue with
24 the opiate epidemic, and it's just an informal
25 discussion of the business practices of that

1 particular distributor.

2 Q. Would you agree that it sounds like a
3 pretty healthy and good thing to do?

4 MS. BACCHUS: Objection.

5 MR. SHKOLNIK: Objection.

6 THE WITNESS: I agree it's an effective
7 initiative, yes.

8 BY MR. NICHOLAS:

9 Q. And it was put on hold for 11 years?

10 A. No. There's a gap there. It started in
11 2005. It was put on hold -- I'm told from my at
12 the time section chief that it was put on hold in
13 about 2013.

14 Q. 2013?

15 A. Yeah. Yeah, it was put on hold.

16 Q. Why?

17 A. Resources, just having enough of her
18 staff, and this is a conversation I had with my
19 section chief at the time, that they had a lot on
20 their plate at the time, a lot of initiatives, and
21 they just didn't have the staff to support it at
22 the time.

23 Q. So it was on hold, in your recollection,
24 for the three years from 2013 to 2016?

25 A. Yeah, and that's a guess, but around that

1 time.

2 Q. Now, if you look at No. 1 in Mr. Haddox's
3 list of things that you talked about, he writes she
4 made frequent references to, quote, different
5 management, unquote, at DEA implying a very
6 different philosophy and approach than has existed
7 in the recent past.

8 Is that an accurate statement description
9 by him?

10 A. Yeah, I guess I agree with that.

11 Q. Finally, can you look at No. -- can you
12 look at subparagraph 9, the last thing under
13 Mr. Haddox's e-mail. He writes she stated an NPRM
14 regarding suspicious order monitoring may appear in
15 the Federal Register in the spring of 2017. She
16 said DEA has been had been interacting with
17 registrants to enable them to propose a reasonable
18 rule.

19 Do you see that?

20 A. Yes.

21 Q. Okay. Did you say that at the meeting, or
22 do you recall reporting about that?

23 A. I don't recall, but it's likely.

24 Q. Is it true?

25 A. Is this true? The statement as it's

1 written, no.

2 Q. What's untrue about it?

3 A. I likely said that we were working on a
4 suspicious order monitoring. Appearing in spring
5 of 2017, I don't recall that.

6 Q. Let me just ask you as of this date at
7 least, the day he wrote this e-mail, which is
8 October of 2016, was the DEA working on possible
9 changes to the suspicious order monitoring
10 regulation?

11 A. Yes.

12 Q. When did the DEA begin working on possible
13 changes to the suspicious order monitoring
14 regulation?

15 A. So I wouldn't -- I guess I'm not clear on
16 where to begin. The discussions?

17 Q. Yeah.

18 A. The discussions would have been early
19 2016.

20 MR. NICHOLAS: Let's take a break. On the
21 theory we've gone more than an hour, let's take a
22 break.

23 THE VIDEOGRAPHER: We're off the record at
24 10:38 a.m.

25

1 (Whereupon, a short break was
2 taken.)

3 THE VIDEOGRAPHER: We are back on the record at
4 10:59 a.m.

5 BY MR. NICHOLAS:

6 Q. During the course of your time -- let me
7 start again by saying back on the record. Hi.
8 Let's keep going.

9 During the course of your time at the DEA,
10 did the DEA communicate with industry groups or
11 trade associations such as HDMA?

12 MS. BACCHUS: Objection. Scope.

13 THE WITNESS: I did, yes.

14 BY MR. NICHOLAS:

15 Q. Was HDMA the industry group for the
16 distributors?

17 A. Yes.

18 Q. Did it later come to be referred to as
19 HDA?

20 A. Yes.

21 Q. Have you spoken at HDMA conferences?

22 A. I don't recall.

23 Q. At any time during your tenure at the DEA,
24 did you learn that the distributors were confused
25 about their suspicious order regulations and wanted

1 more guidance from the DEA?

2 A. I can say in speaking with distributors,
3 they expressed that they wanted more clarification.

4 Q. And so you heard that directly from the
5 distributors?

6 A. Yes.

7 Q. Okay. Did you also hear it from HDA, if
8 you remember?

9 A. I have to ask a question. Is John Gray --

10 Q. Yes.

11 A. Yes. Yes.

12 Q. So just for the record, I'm being terrible
13 about this. We should do this properly. Do you
14 know who John Gray is?

15 A. Yes.

16 Q. Is he the head of HDMA, now HDA?

17 A. He was when I was with DEA.

18 Q. And you communicated with him?

19 A. Yes.

20 Q. And he expressed concerns to you about the
21 distributors seeking more clarification or clarity
22 as to the suspicious order reporting requirements?

23 A. Yes.

24 Q. How often would you do that, would you
25 say?

1 A. I don't recall exactly. I spoke with him
2 a few times.

3 Q. Do you remember -- what was it -- if you
4 remember, what was it that he was saying they were
5 confused or needed clarification about?

6 A. They wanted specific clarification on when
7 and when not to ship. They wanted, in my opinion,
8 DEA to make the call on when they should and should
9 not ship. John just expressed that DEA wasn't
10 being clear, and I expressed back I felt that we
11 were clear.

12 Q. Okay. What is the earliest that you
13 recall hearing that the distributors wanted more
14 clarification?

15 MR. NICHOLAS: Let's go off the record.

16 THE VIDEOGRAPHER: We're off the record at
17 11:03 a.m.

18 (Whereupon, a short break was
19 taken.)

20 THE VIDEOGRAPHER: We're back on the record at
21 11:04 a.m.

22 BY MR. NICHOLAS:

23 Q. Do you know or remember when you first
24 started hearing from John Gray on these issues?

25 MS. BACCHUS: Objection. Vague. What issues?

1 MR. NICHOLAS: I'll clarify.

2 BY MR. NICHOLAS:

3 Q. Do you recall when you first started
4 hearing from John Gray that the distributors were
5 looking for more clarity in connection with the
6 suspicious order monitoring requirements?

7 A. The first time I can recall was in
8 February of 2016 when we held a -- DEA hosted a
9 meeting with registrant organizations and HDA was
10 one of them. So there were several organizations
11 that were present, and I think that's the first
12 time I met John Gray. I don't recall, but I think
13 it was.

14 Q. Do you recall Mr. Gray also communicating
15 that the distributors were seeking clarification as
16 to what constituted a suspicious order?

17 A. Yes.

18 MR. NICHOLAS: I'd like to mark as the next
19 exhibit Ashley 8.

20 (Whereupon, ASHLEY Deposition
21 Exhibit No. 8 was marked for
22 identification.)

23 BY MR. NICHOLAS:

24 Q. Ashley 8 is a letter with an attachment.
25 The letter is from Mr. Gray, John Gray, to Michelle

1 Leonhart at the DEA. It's dated June 1, 2011, and
2 it attaches a summary of a meeting that was held
3 between the DEA and HDMA on December 7th of 2010.

4 Do you recall -- have a recollection of
5 this document?

6 A. I do not.

7 Q. Okay. Do you see that the document is
8 sent to Ms. Leonhart and CC to Joseph Rannazzisi
9 and Kathy Gallagher?

10 A. Yes.

11 Q. Who is -- what was Kathy Gallagher's role
12 at this period of time on June 1, 2011?

13 A. She was in headquarters as the acting
14 section chief of liaison and policy.

15 Q. So am I correct that this letter from John
16 Gray -- I should ask you also who is Michelle
17 Leonhart?

18 A. Michelle Leonhart was the administrator
19 for DEA. I believe she retired in 2015.

20 Q. Okay. So am I correct that this letter
21 was really going to the top brass at DEA?

22 MS. BACCHUS: Objection.

23 BY MR. NICHOLAS:

24 Q. To leadership?

25 A. Yeah. That's Michelle Leonhart.

1 Q. And Mr. Rannazzisi and Ms. Gallagher, they
2 were all sort of in senior leadership roles?

3 A. Yes.

4 Q. Now, Ms. Leonhart encloses a document, and
5 I'm not going to subject you to the whole document,
6 but I am going to ask you a few questions about
7 what's inside it if that's okay. If you look at
8 the summary of the DEA HDMA meeting itself, the
9 first page of it, and you go to the section that's
10 headed -- well, let's start with the first sentence
11 of the introduction just so we know what we're
12 looking at here.

13 This was a meeting that was requested by
14 HDMA of the DEA. Can you see that from the first
15 sentence of the letter?

16 A. Yes.

17 Q. And now let's go to the key HDMA
18 discussion points and look at the second full
19 paragraph. It says HDMA pointed out that while
20 much of the DEA guidance on controlled substance
21 suspicious order monitoring indicates wholesale
22 distributors' legal responsibilities, its practical
23 value is more limited. It then goes -- do you see
24 that?

25 A. I see that.

1 Q. It then goes on to say for example, the
2 current regulatory guidance indicates that, quote,
3 suspicious orders include orders of unusual size,
4 orders deviating substantially from a normal
5 pattern and orders of unusual frequency. This
6 certainly identifies appropriate themes on which
7 the wholesale distributor should base their
8 suspicious orders monitoring programs, but it is
9 also very subjective.

10 Do you agree with that?

11 A. I agree that it's subject to the
12 distributor, yes.

13 Q. And that it's subjective?

14 MR. SHKOLNIK: Objection to form.

15 MS. BACCHUS: Is there a question?

16 MR. NICHOLAS: Yeah.

17 BY MR. NICHOLAS:

18 Q. Do you also agree that there is
19 subjectivity -- well, strike that.

20 Do you agree with the next sentence that
21 says patterns can vary greatly or over time or even
22 with a single customer?

23 A. I agree with that, yes.

24 Q. Now, at this point, this is 2010. You're
25 in Chicago, correct?

1 A. Yes.

2 Q. Okay. So you're -- so you're in a
3 supervisory position, but you're in the field.
4 You're not in headquarters?

5 A. Correct.

6 Q. Did headquarters ever inform its
7 leadership in the field like you that the
8 distributors had raised these concerns?

9 MS. BACCHUS: Objection. Form.

10 THE WITNESS: I don't recall directly from
11 headquarters. We were engaging -- myself, I was
12 engaging with the distributors in my division.

13 BY MR. NICHOLAS:

14 Q. So you were aware of these kinds of
15 concerns from the distributors already?

16 A. I wouldn't say it that way. I would just
17 say that I had several discussions with
18 distributors about their suspicious order
19 monitoring.

20 Q. Well, then let me ask you were you aware
21 of the concerns, specific concerns raised in the
22 paragraph I just read to you?

23 MR. SHKOLNIK: Objection.

24 MS. BACCHUS: Objection. Asked and answered.

25

1 BY MR. NICHOLAS:

2 Q. Were you aware of them from the
3 distributors?

4 MR. SHKOLNIK: Objection. Asked and answered
5 line by line.

6 THE WITNESS: So I would have to say no, not
7 these specific things.

8 BY MR. NICHOLAS:

9 Q. Okay. Would it have been helpful for you
10 to hear this from leadership that the distributors
11 were raising these specific things?

12 MR. SHKOLNIK: Objection. Outside the scope.

13 MS. BACCHUS: Objection. Calls for
14 speculation.

15 THE WITNESS: I would have to say I don't
16 recall. They -- we had several trainings, so I
17 don't recall.

18 BY MR. NICHOLAS:

19 Q. Well, is this the kind of information that
20 it's helpful for you to know?

21 A. Yes.

22 Q. If you go to the next page, HDMA
23 recommendations, it says that HDMA encouraged DEA
24 to take the following steps, and there are four
25 bullet points. I'm only going to ask you about

1 three of them. Let's start with the first one.

2 The first bullet point reads provide
3 better clarifications in writing and with the
4 opportunity for public comment of wholesale
5 distributors' responsibilities for suspicious
6 orders monitoring. HDMA emphasized the need for
7 more specificity on what constitutes a suspicious
8 order and on DEA's expectations for what wholesale
9 distributors must do to monitor, identify and
10 report.

11 A. I'm sorry. I'm not on the same page as
12 you.

13 Q. I'm sorry. It's Page 2 of the summary.

14 A. Okay.

15 Q. We can take a step back.

16 A. I have it.

17 Q. It's four bullet points in the middle. Do
18 you see that? These are HDMA recommendations, and
19 it says HDMA encouraged DEA to take the following
20 steps. I'll read it again. I'll read the first
21 paragraph -- the first bullet point again.

22 The first bullet point is, and I should
23 say -- I should be clearer about this. It says
24 HDMA encouraged DEA to take the following specific
25 steps. First bullet point, provide better

1 clarifications in writing and with the opportunity
2 for public comment of wholesale distributors'
3 responsibilities for suspicious orders monitoring.
4 HDMA emphasized the need for more specificity on
5 what constitutes a, quote, suspicious order and on
6 DEA's expectations for what wholesale distributors
7 must do to monitor, identify and report. Do you
8 see that?

9 A. Yes.

10 Q. Now, let's start with this one. To your
11 knowledge, has the DEA acted on this specific step?

12 MR. SHKOLNIK: Objection. This is -- sorry.

13 MS. BACCHUS: Objection. She can't testify on
14 behalf of DEA. She can testify about her personal
15 knowledge to the extent she knows.

16 MR. NICHOLAS: Okay.

17 MR. SHKOLNIK: And objection. The problem here
18 is the DEA's response is listed on this letter, and
19 you're asking for her opinion and her recollection,
20 and that's inappropriate. It's outside the scope
21 of what we were told were the limitations.

22 BY MR. NICHOLAS:

23 Q. To your knowledge, has the DEA acted with
24 regard to this specific step that was requested by
25 HDMA?

1 A. Has DEA acted on providing better
2 clarification for suspicious order monitoring?

3 Q. Better clarifications in writing and with
4 the opportunity for public comment.

5 A. Yes.

6 Q. In what format has the DEA provided
7 written clarification of the suspicious order
8 monitoring requirement?

9 MS. BACCHUS: Again, objection to scope. She
10 can't testify on behalf of DEA.

11 MR. NICHOLAS: I'm just asking about her
12 personal knowledge.

13 THE WITNESS: In my personal knowledge, you're
14 saying providing in writing. I was -- I understood
15 the question as has DEA acted on it, which would
16 be, you know, the discussions, the meeting and
17 engagement with registrants and that sort of thing.
18 So I was encompassing all of it, not just in
19 writing.

20 BY MR. NICHOLAS:

21 Q. To your knowledge, your personal
22 knowledge, has any further writing, written
23 clarification been issued from 2010 until today
24 from the DEA?

25 MR. SHKOLNIK: Objection.

1 THE WITNESS: From my personal knowledge and
2 management over the policy and liaison section, I
3 know there were letters drafted and responding to
4 industry questions on suspicious orders. So there
5 were written communications.

6 BY MR. NICHOLAS:

7 Q. Has the DEA, in your personal knowledge,
8 provided any additional written definition of what
9 a suspicious order is?

10 MR. SHKOLNIK: Objection.

11 THE WITNESS: Published publicly, no.

12 BY MR. NICHOLAS:

13 Q. Published anywhere?

14 A. No.

15 Q. To your personal knowledge, has the DEA
16 been giving consideration to doing this for a
17 period of time?

18 MS. BACCHUS: Objection.

19 THE WITNESS: The period of time to my
20 knowledge, yeah, beginning 2015.

21 BY MR. NICHOLAS:

22 Q. So to your personal knowledge, since 2015,
23 DEA has been giving consideration to providing an
24 additional definition of a suspicious order?

25 A. Yes.

1 Q. And that that definition has not yet been
2 forthcoming; is that correct?

3 MR. SHKOLNIK: Objection.

4 MS. BACCHUS: Objection.

5 THE WITNESS: I don't believe so.

6 BY MR. NICHOLAS:

7 Q. Okay. And according to this document,
8 HDA, speaking for -- on behalf of its constituent
9 distributors, was asking for written clarification
10 of the definition of a suspicious order as early as
11 2010.

12 MR. SHKOLNIK: Objection.

13 MS. BACCHUS: Objection.

14 BY MR. NICHOLAS:

15 Q. Is that right?

16 MS. BACCHUS: The witness said she hasn't seen
17 the document.

18 THE WITNESS: This document, I've never seen
19 it.

20 BY MR. NICHOLAS:

21 Q. But looking at it, does it appear --

22 A. It appears looking at the document, yes.

23 Q. Okay. Let's go to the second point, the
24 second bullet point. HDA asked that the DEA update
25 the, quote, letters to industry provided in 2006

1 and 2007. Do you see that?

2 A. Yes.

3 Q. And those letters to industry, are
4 those -- to your understanding, would that be a
5 reference to the letters that Mr. Rannazzisi wrote,
6 the dear registrant letters in 2006 and 2007?

7 A. Yes.

8 MS. BACCHUS: Objection. Vague.

9 THE WITNESS: Yes.

10 BY MR. NICHOLAS:

11 Q. To your knowledge, were there updated
12 letters to industry provided after 2007?

13 A. I don't recall that.

14 Q. Let's look at the -- hold on. So you
15 don't recall -- so sitting here today, you don't
16 recall any such letters; is that right?

17 MR. SHKOLNIK: Objection to form.

18 MS. BACCHUS: Objection.

19 THE WITNESS: The dear registrant letters of
20 this type, I don't.

21 BY MR. NICHOLAS:

22 Q. Okay. Let's go to bullet point 4, provide
23 wholesale distributors -- the bullet point reads as
24 follows. This is the fourth specific step that HDA
25 is encouraging DEA to take. It reads provide

1 wholesale distributors with an indication of when,
2 based on the DEA analysis of automation of reports
3 and consolidated orders system, parentheses, ARCOS,
4 or other data, there is reason to believe a
5 customer's order may be considered suspicious.

6 HDMA noted its understanding that this request
7 previously made in a letter from HDMA dated July 7,
8 2010 has been under consideration within the DEA.

9 So in this letter, so in this bullet
10 point, HDA appears to be or is asking for the DEA
11 to provide it with information from the ARCOS data;
12 is that correct?

13 MS. BACCHUS: Objection.

14 THE WITNESS: Yes.

15 MS. BACCHUS: That's beyond the scope of what
16 she's authorized to testify. She's not allowed to
17 testify about the ARCOS database.

18 MR. NICHOLAS: I'm not asking her -- I don't
19 want her to testify about the database. I just
20 want to know whether in this -- whether it appears
21 from this correspondence that HDA was asking for
22 ARCOS-related information.

23 MR. SHKOLNIK: Note my objection, a similar
24 objection. It's outside the scope of what this
25 witness is supposed to be testifying about.

1 BY MR. NICHOLAS:

2 Q. You can go ahead and answer to the best of
3 your knowledge.

4 A. To the best of my knowledge, this letter,
5 that's their request, HDA's request, yes.

6 Q. Now, to your knowledge, without describing
7 anything about the ARCOS database, did DEA ever
8 take a step in response to bullet point No. 4?

9 MR. SHKOLNIK: Objection.

10 MS. BACCHUS: Objection.

11 MR. SHKOLNIK: The witness is not supposed to
12 be testifying to DEA's actions.

13 BY MR. NICHOLAS:

14 Q. You can answer.

15 A. I don't know if they took steps to respond
16 to this bullet point.

17 Q. Not to your knowledge?

18 A. Not to my knowledge.

19 MR. SHKOLNIK: Objection to form.

20 BY MR. NICHOLAS:

21 Q. Okay. The only other thing I need to ask
22 you about this document, Ms. Ashley, is I just want
23 you to take a look at the rest of the document.

24 I'm not going to ask you to read it. I just want
25 you to page through it. There's a part of -- the

1 rest of this summary of the meeting with DEA is
2 comprised of questions that HDA submitted to the
3 DEA that it was hoping to have answered, and I'm
4 not going to ask you about any of the specific
5 questions.

6 Can you just page through to see that
7 there were a number of pages of questions? In
8 fact, there were 12 pages of questions, which HDA
9 submitted to the DEA. Do you see that?

10 A. I do.

11 Q. Now we can go to the next document. Do
12 you know -- you haven't seen this document before,
13 so you haven't seen these questions before, so --
14 but I'll ask anyway.

15 Do you know whether the DEA ever responded
16 to these questions?

17 MS. BACCHUS: Objection.

18 MR. SHKOLNIK: Objection.

19 THE WITNESS: I don't know.

20 BY MR. NICHOLAS:

21 Q. Were you ever consulted about responding
22 to these questions?

23 MS. BACCHUS: Objection. That's vague. Which
24 document are we talking about?

25

1 BY MR. NICHOLAS:

2 Q. The questions that we just looked at, the
3 series of questions in the exhibit we were just
4 looking at.

5 MR. SHKOLNIK: Note my objection.

6 MS. BACCHUS: I'm sorry. She has to review the
7 whole questions then if you want her to find out if
8 she responded to any of the questions.

9 MR. NICHOLAS: Okay. I appreciate the
10 objection. I'm going to respect it, and I'm going
11 to move on to the next.

12 MR. SHKOLNIK: Are you withdrawing the question
13 so it's clear on the record?

14 MR. NICHOLAS: I've already said what I'm going
15 to say about it.

16 MR. SHKOLNIK: Well, then it's an open
17 question. It has to be answered. Either withdraw
18 it or let her answer.

19 MR. NICHOLAS: I'm going to just move on.

20 MR. SHKOLNIK: No. You can't leave an open
21 question. You have to withdraw it, or she answers
22 it. You can move on all you want. Just say
23 withdraw it. It's not a --

24 MR. NICHOLAS: I'm going to move on from the
25 last question.

1 MR. SHKOLNIK: Do we need to go to a special
2 master? Are you leaving an open question on the
3 record? Either the witness answers it or you
4 withdraw it.

5 MR. NICHOLAS: I'm actually going to withdraw
6 it, but is there a rule that says that?

7 MR. SHKOLNIK: Yeah.

8 MR. NICHOLAS: What is the rule?

9 MR. SHKOLNIK: Are you withdrawing it?

10 MR. NICHOLAS: No. What's the rule?

11 MR. SHKOLNIK: Are you withdrawing it?

12 MR. NICHOLAS: I'll tell you what. I'll tell
13 you what. I'm going to withdraw it. What is the
14 rule?

15 MR. SHKOLNIK: Thank you.

16 MR. NICHOLAS: What's the rule?

17 MR. SHKOLNIK: That when you pose a question,
18 you have to have an answer.

19 MR. NICHOLAS: So there's no rule. I've got
20 it. You just wanted me to do that. I did it for
21 you.

22 BY MR. NICHOLAS:

23 Q. Let's go to -- let's go to the next
24 document.

25 MR. NICHOLAS: We'll make this Ashley 9.

1 (Whereupon, ASHLEY Deposition
2 Exhibit No. 9 was marked for
3 identification.)

4 BY MR. NICHOLAS:

5 Q. Take a minute to look at this document.
6 This is a document which you have seen, I believe.
7 What I've given you is, working from front to back,
8 an e-mail to you from Louis Milione sent on
9 June 22nd of 2016. The subject is follow-up from
10 HDA board meeting -- forward of a follow-up from an
11 HDA board meeting, and there are two attachments to
12 this e-mail to you from 2016. One is final final
13 questions from DEA -- for DEA 6/1/11, and the
14 second attachment is final HDMA questions for DEA
15 discussion on 7/13/31. Excuse me, 7/31/13.

16 And Mr. Milione has forwarded to you an
17 e-mail from John Gray to Mr. Milione that Mr. Gray
18 sent on June 22, 2016 in which Mr. Gray references
19 a meeting that was recently held where Mr. Milione
20 addressed HDA's board of directors. Do you see
21 that?

22 A. Yes.

23 Q. And then in that same e-mail, Mr. Gray
24 attaches documents that are five years and three
25 years old respectively, and what Mr. Gray says is

1 per our discussion, here are the documents I
2 referenced during the meeting. These documents are
3 now five and three years old respectively, but we
4 are submitting them for your information as an
5 example of previous efforts to develop a better
6 understanding of DEA's expectations about
7 suspicious order monitoring and to ask for guidance
8 when there are questions -- when there were
9 questions about situations that arose in day-to-day
10 operations.

11 While the receipt of these questions was
12 acknowledged by DEA staff, parentheses, Kathy
13 Gallagher, we never received a response to any of
14 the questions or scenarios addressed in the
15 correspondence. The attached 2013 questions were
16 supposed to serve as a sort of agenda for a meeting
17 with the Office For Diversion Control, but that
18 meeting was cancelled with relatively little
19 notice. And then Mr. Milione wrote to you I
20 haven't read these yet, referring to the questions
21 in the attachments, but can we look at them and get
22 something out if appropriate?

23 Do you remember this?

24 A. I don't remember it.

25 Q. Okay. Are you surprised that neither

1 Ms. Gallagher nor anyone else at the DEA responded
2 to these questions over the course of three and
3 five years?

4 MS. BACCHUS: Objection.

5 MR. SHKOLNIK: Objection to form.

6 THE WITNESS: My personal opinion, yeah, I'm
7 surprised.

8 BY MR. NICHOLAS:

9 Q. What happened with this? Did you -- did
10 you work to draft answers to these questions?

11 A. I don't remember specifically.

12 Q. Do you know whether these questions were
13 ever answered?

14 A. I don't remember, no. I don't.

15 Q. Do you know whether DEA ever responded to
16 these questions in any way, whether written or
17 verbal?

18 MS. BACCHUS: Objection. She can answer to her
19 personal knowledge.

20 BY MR. NICHOLAS:

21 Q. Yeah, only from your personal knowledge.

22 A. I'm sorry. Could you repeat that?

23 Q. Do you know if there was any response ever
24 provided to these questions provided by the DEA
25 whether written or verbal?

1 A. I know that we were responsive to John
2 Gray, so verbally I'm certain we spoke to him. I
3 don't recall if we wrote, if there was anything in
4 writing.

5 Q. Do you know why not?

6 MS. BACCHUS: Objection.

7 THE WITNESS: I don't recall --

8 MR. SHKOLNIK: Objection. Misstatement.

9 THE WITNESS: -- if it happened.

10 BY MR. NICHOLAS:

11 Q. Now, we just reviewed a document which
12 shows that HDA was seeking more written guidance as
13 early as 2010, right?

14 A. Yes.

15 Q. And they were also asking for new dear
16 registrant letters from the DEA that would provide
17 more guidance and explanation, right?

18 A. Yes.

19 Q. And to your knowledge, they never got
20 those things, right?

21 MR. SHKOLNIK: Objection.

22 MS. BACCHUS: Objection. Mischaracterizes her
23 testimony.

24 BY MR. NICHOLAS:

25 Q. Go on. To your knowledge.

1 A. To my knowledge, I would have to say no, I
2 don't know.

3 Q. Now, you had the pleasure of testifying
4 before Congress in 2017; is that right?

5 A. Yes.

6 Q. And you had a prepared statement in
7 connection with that testimony, right?

8 A. Yes.

9 Q. I've never seen anyone cross their eyes on
10 camera before.

11 A. Bad habit.

12 Q. I'm going to mark as the next exhibit your
13 prepared statement.

14 (Whereupon, ASHLEY Deposition
15 Exhibit No. 10 was marked for
16 identification.)

17 BY MR. NICHOLAS:

18 Q. You probably have a memory of this. I'm
19 actually only going to ask you about what you said
20 at the very end. If you go to the last page,
21 Page 8, just before the conclusion, I'm going to
22 read, if you don't mind, the paragraph that's
23 written just before the conclusion. You wrote and
24 submitted to Congress the following:

25 As we move forward, we recognize the

1 importance of working with registrants, dash, not
2 just at workshops and conferences, dash, but in
3 writing that they can count on, dash, to provide
4 them all the information and especially the
5 certainty that they need to be in full compliance,
6 comma, as they want to be -- as they want to be and
7 as we expect them to be.

8 Do you see that?

9 A. Yes.

10 Q. Let's just break down that paragraph.

11 Why is it so important to work with
12 registrants?

13 A. It helps to ensure compliance. It's part
14 of DEA's, Office of Diversion Control, mission to
15 secure an -- ensure an adequate supply of controls
16 and also to detect diversion. So in order to do
17 that effectively, you have to engage with the
18 registrants.

19 Q. And why is written guidance to registrants
20 so important?

21 MR. SHKOLNIK: Objection. Speaking on behalf
22 of DEA or her personal opinion?

23 MR. NICHOLAS: I'm asking about a statement
24 that Ms. Ashley made to Congress. She can speak
25 personally if you'd like.

1 MR. SHKOLNIK: No. I'm asking is it personal
2 or DEA just so it's clear?

3 MS. BACCHUS: Well, she's only authorized to
4 testify on her personal knowledge on her own
5 behalf, not on behalf of DEA. That's a standing
6 objection that she can't speak on behalf of DEA.

7 BY MR. NICHOLAS:

8 Q. Okay. I'll restate the question, but
9 first I'll ask you what was your position at the
10 time that you gave this testimony?

11 A. I was acting assistant administrator.

12 Q. Now, why was it important -- strike that.
13 Why is written guidance to registrants so
14 important?

15 MR. SHKOLNIK: Objection. Same objection.
16 Personal?

17 BY MR. NICHOLAS:

18 Q. Go ahead.

19 A. For me personally, it creates a reference
20 document for the registrant to use as they work to
21 ensure compliance. So it's a reference for them.

22 Q. And if theres's not a reference document,
23 in your personal experience, does that create
24 ambiguity?

25 A. I don't know because I don't know if

1 there's not a reference document. So I'm not sure
2 if I understand the question.

3 Q. Well --

4 A. Reference documents specific to what?

5 Q. Was the DEA -- now, to your knowledge, the
6 DEA at this time and previously was working to
7 create additional written guidance for the
8 distributor community, correct?

9 A. Correct.

10 Q. And to your knowledge, it was doing that
11 why?

12 A. It was doing it because registrants and
13 DEA wanted to work together to provide more
14 clarification.

15 Q. And why was that?

16 MS. BACCHUS: Objection. Vague.

17 BY MR. NICHOLAS:

18 Q. In your opinion.

19 MR. SHKOLNIK: Objection to form.

20 THE WITNESS: In my opinion, because we were
21 getting the conversation in our engagements with
22 registrants that they were not clear, so we were
23 working with them to make it more clear for them to
24 help them to be in compliance.

25

1 BY MR. NICHOLAS:

2 Q. Do you believe there was a need for
3 further written guidance?

4 MR. SHKOLNIK: Objection.

5 MS. BACCHUS: Objection. Calls for opinion.

6 THE WITNESS: Personally I thought the existent
7 regulation was clear.

8 BY MR. NICHOLAS:

9 Q. You wrote and submitted to Congress
10 that -- about the importance of working with
11 registrants, and I don't want to read the whole
12 thing again. I'm just going to the last part to
13 say to provide them all the information and
14 especially the certainty that they need to be in
15 full compliance, comma, as they want to be and as
16 we expect them to be.

17 In your experience, in your personal
18 experience, did the registrants, i.e., the
19 distributors, want to be in full compliance?

20 A. For the most part, yes.

21 Q. Okay. Let's go back and talk for a few
22 minutes about the suspicious order regulation as it
23 still currently exists, CFR 1301.74, Subsection B.
24 This is Ashley 3.

25 Now, as we discussed, you're familiar with

1 this regulation, correct?

2 A. Yes.

3 Q. And it first came out in 1971; is that
4 right?

5 A. I believe so, yes.

6 Q. And this is the regulation that addresses
7 the responsibilities of the distributors to
8 identify and report suspicious orders; is that
9 right?

10 A. Yes.

11 Q. And it says that registrants, quote, shall
12 design and operate a system to disclose the
13 registrant's suspicious orders of controlled
14 substances, correct?

15 A. Yes.

16 Q. Do you -- are you able to -- from your
17 experience both in the field and in headquarters,
18 are you able to define for the distributors or tell
19 them or have you been able to tell them what
20 constitutes a legally compliant system?

21 MS. BACCHUS: Objection to form.

22 MR. SHKOLNIK: Objection to form. Outside the
23 scope.

24 BY MR. NICHOLAS:

25 Q. Go ahead.

1 A. No. That was never my role.

2 Q. To your knowledge, is there a particular
3 formula or algorithm that is required for a legally
4 compliant system?

5 A. To my knowledge --

6 MS. BACCHUS: Same objection.

7 MR. SHKOLNIK: Objection.

8 BY MR. NICHOLAS:

9 Q. Go ahead.

10 A. To my knowledge, there is not.

11 Q. To your knowledge, does a legally
12 compliant system need to be automated?

13 A. No, it does not.

14 Q. Does it need to be manual, i.e., the
15 opposite of automated?

16 MS. BACCHUS: Objection. Vague.

17 THE WITNESS: It's not specific. There's no
18 direction on how to do it.

19 BY MR. NICHOLAS:

20 Q. Are there particular methods of
21 investigation that are required in order for a
22 system to be legally compliant?

23 A. Yes.

24 Q. What are they?

25 A. The method would be to -- as it's outlined

1 in the regulation, to take a look at the order,
2 make a determination if it's deviating from what's
3 usual. I mean, how you do it, it can be manual or
4 automatic, but it's just that it needs to be done.

5 Q. And the criteria that determines whether
6 it deviates from pattern or too large or anything
7 else is criteria that is to be set by the
8 distributors?

9 A. Correct.

10 Q. And so it's within their discretion; is
11 that correct?

12 A. That's correct.

13 Q. And is it correct that the distributors
14 must define their own parameters for a suspicious
15 order?

16 A. There's some regulation requirement that
17 it be effective. So other than that, it's their
18 discretion, but it just must be effective.

19 Q. And whether a system is effective is in
20 itself a subjective determination; isn't that
21 correct?

22 A. Yes, I would agree with that.

23 Q. Okay. Are you aware that the United
24 States Government Accountability Office, the GAO,
25 issued a report in June of 2015 that stated that

1 distributors wanted more guidance and regular
2 communications with the DEA regarding suspicious
3 order monitoring and guidance?

4 A. I am aware of the report. That specific
5 statement, I can say I don't recall, but I did read
6 the report.

7 Q. Well, I was paraphrasing, obviously.

8 A. Yeah.

9 Q. Was my paraphrase accurate?

10 A. I believe so.

11 MR. SHKOLNIK: Objection. Form.

12 BY MR. NICHOLAS:

13 Q. You can go ahead.

14 MS. BACCHUS: If you know.

15 THE WITNESS: Yeah. I mean, I'm certain, but I
16 believe it's in there. I'm not -- I believe it's
17 in there. I read the report in 2015.

18 BY MR. NICHOLAS:

19 Q. What is the GAO? What is the Government
20 Accountability Office?

21 A. They're oversight to ensure that
22 government agencies are, you know, focused in
23 performing their duties and their mission.

24 Q. Were you interviewed in connection with
25 their preparation, with GAO's preparation of that

1 report?

2 A. I was not, no.

3 MR. NICHOLAS: Let's mark the report. This is
4 Ashley 11.

5 (Whereupon, ASHLEY Deposition
6 Exhibit No. 11 was marked for
7 identification.)

8 BY MR. NICHOLAS:

9 Q. All right. If you look at the very --
10 let's see. If you look at the very first page
11 after the cover page on the inside, there's a
12 little column that says GAO highlights. Do you see
13 that?

14 A. Yes.

15 Q. It says why GAO did this study.

16 MR. SHKOLNIK: I'm sorry. Which page?

17 MR. NICHOLAS: It's -- it's the inside. It's
18 the other side of the cover.

19 BY MR. NICHOLAS:

20 Q. You'll see that it says -- there's a
21 column on the left side that says why GAO did this
22 study, and it says in the second paragraph GAO was
23 asked to review registrants' and other's
24 interactions with DEA, and then it goes on to say
25 more. And then there's -- under that, there's a

1 heading that says what GAO recommends, and it says
2 GAO recommends DEA take three actions to improve
3 communication with and guidance for registrants
4 about the CSA roles and responsibilities. DEA
5 described actions that it planned to take to
6 implement GAO's recommendations. However, GAO
7 identified additional actions GAO should take to
8 fully implement their recommendations.

9 Do you see that?

10 A. Yes.

11 Q. So let's turn to the recommendations
12 themselves.

13 MS. BACCHUS: I'm going to object to this
14 document and her answering any questions regarding
15 this GAO report. It's outside of the scope of her
16 Touhy authorization.

17 MR. NICHOLAS: So I would reference in response
18 to that -- we'll go off the record for a minute.

19 THE VIDEOGRAPHER: Off the record at 11:54 a.m.
20 (Whereupon, a short break was
21 taken.)

22 THE VIDEOGRAPHER: We're back on the record at
23 12:07 p.m.

24 MR. NICHOLAS: I've considered the objection,
25 and the government has made a representation to me

1 that another witness or other witnesses have been
2 designated to testify about the GAO report. So on
3 that representation, I will not ask any questions
4 about -- won't ask any further questions about the
5 report.

6 BY MR. NICHOLAS:

7 Q. Now, we've spent some time already talking
8 about the fact that the DEA has considered and is
9 considering modifying the suspicious order
10 regulation, the written regulation, right?

11 A. Right.

12 MR. SHKOLNIK: Objection to form.

13 BY MR. NICHOLAS:

14 Q. Go ahead.

15 A. Yes.

16 Q. Was this process under way, this
17 consideration under way when you first joined
18 headquarters in 2015?

19 A. I don't know.

20 Q. Who at the DEA is in charge of the process
21 of considering revision to the suspicious order
22 monitoring regulation?

23 A. It begins with the administrator, and then
24 after that, it would be the assistant administrator
25 for the diversion control division.

1 MR. NICHOLAS: Can we mark the next exhibit,
2 please.

3 (Whereupon, ASHLEY Deposition
4 Exhibit No. 12 was marked for
5 identification.)

6 BY MR. NICHOLAS:

7 Q. Ms. Ashley, I've asked you to take a look
8 at the next exhibit, which is Ashley 12. And for
9 the record, this is a document, which, among
10 others, the government told us they wanted to claw
11 back. They told us this morning. We'll reserve
12 our rights as to it, but on a positive note, we
13 were able to work with the government to redact
14 portions of the document. So we're going to be
15 using the redacted version of the document. We'll
16 reserve our rights to discuss the document further
17 at a future time, but in order to have the
18 deposition move forward, we'll just use this
19 document, and that will -- that's what we'll do.

20 What I've given you, Ms. Ashley, is an
21 e-mail stream, which ends with an e-mail from
22 Mr. Milione to Imelda Paredes and John Scherbenske.
23 These are all DEA people writing to each other, but
24 it contains a stream of e-mails that begins on
25 September 30, 2015 at 12:39 a.m. with an e-mail --

1 I'm sorry. I'm not even right about that. It
2 doesn't have it. It begins with an e-mail from you
3 to Imelda Parades, who, I guess, her nickname is
4 Mimi?

5 A. Mimi.

6 Q. You wrote to her sometime before
7 September 30, 2015 because that's when the next
8 e-mail is, and you wrote to Ms. Paredes and said
9 hi, Mimi. I hope you're doing well. In regards to
10 the CC suspicious order document, dash, have you
11 reviewed it, do you have any notes, response,
12 communication with CC on their document? If so,
13 would you please share it, slash, them with me.
14 Thank you.

15 Does this document refresh your memory as
16 to whether at least as of this date of
17 September 30, 2015 or a little earlier, the DEA was
18 giving consideration to written revisions to the
19 suspicious order monitoring regulation we've been
20 talking about?

21 MR. SHKOLNIK: Objection.

22 THE WITNESS: So this document refreshes my
23 memory that chief counsel had drafted a suspicious
24 order document, and it was provided to me.

25

1 BY MR. NICHOLAS:

2 Q. Okay. And then Ms. Mimi writes you back
3 and says hi there. The suspicious order rule that
4 they drafted, yes, but it's handwritten. I can
5 type them up onto the document and send it to you.
6 At the moment, I'm working on registration
7 renewals, which I will copy you on when I send back
8 to ODW. Do you see that?

9 A. Yes.

10 Q. Tell us what Mimi's position was. What
11 was her role at DEA?

12 A. Mimi was in the executive staff under
13 Mr. Rannazzisi. I believe her title was program
14 executive or something to that effect. I'm not
15 sure, but she worked directly for Mr. Rannazzisi on
16 his executive staff.

17 Q. Okay. And if you page forward, there's
18 some very nice back and forth between you and Mimi
19 in which you're being nice about her leave and
20 everything like that, which is nice, and -- but
21 let's fast forward up in this e-mail chain, I
22 think, all the way to -- all the way to the e-mail
23 on the page that's marked DEA-840008425.

24 And it's the e-mail at the bottom of the
25 page from Mimi to you dated Thursday, October 1,

1 2015 at 3:21 p.m., and she writes to you okay,
2 well, then I'm going to clean up the comments and
3 make them a little more thorough since now I assume
4 the rule is going forward, question mark.

5 Remember, we will need to come up with a reason why
6 we changed our minds, period. Parentheses, in a
7 recent Congressional response on a GAO audit, Lou
8 had decided to say we do not need suspicious order
9 guidance, slash, rule, close, parentheses, period.
10 Do you want to also get Judge Mulrooney's comments
11 on the rule? He saw it a while ago and provided
12 oral comments, but I don't think anything in
13 writing?

14 I'm not going to ask you anything about
15 the substantive comments that were going on with
16 the drafting of the new rule. I will ask you this:
17 Was there a change in the position at the DEA with
18 regard to the need for a new suspicious order
19 guidance or rule?

20 MR. SHKOLNIK: Objection.

21 MS. BACCHUS: Objection.

22 MR. SHKOLNIK: Speaking for the DEA.

23 BY MR. NICHOLAS:

24 Q. To your knowledge.

25 A. Change in the position as to whether or

1 not we need one?

2 Q. Yeah.

3 A. I'd say there was a change in what
4 Mr. Milione stated, which I was aware of, versus
5 you know, as time went on. So yeah, I would say
6 yes.

7 Q. Okay. And what were you aware of with
8 regard to Mr. Milione's change of view?

9 A. When he first reported in 2015, he was
10 having discussions on the Hill, and there were
11 questions, you know, from Congress about DEA's
12 engagement with registrants and clarification on
13 the suspicious order. At the time Mr. Milione and
14 myself felt that the current rule was sufficient,
15 and we may not need to change it. Maybe we would
16 continue to engage and continue to have
17 conversations, and that would make the difference
18 and maybe a rule wasn't necessary, a new rule.

19 Q. Okay. So why was there this change back
20 to we need a new rule?

21 A. Well, after, you know, lots of discussion,
22 I guess we felt comfortable that it wouldn't be so
23 much of a change if we were to put some additional
24 language to what existed. It wasn't anything
25 major, so we felt that okay, we could add some more

1 of our thoughts into the regulation.

2 Q. And the purpose, in your mind, of adding
3 more thoughts, more of your thoughts to the
4 regulation would be to provide further guidance to
5 the distributors; is that correct?

6 MR. SHKOLNIK: Objection.

7 MS. BACCHUS: Objection. Form.

8 THE WITNESS: It would be further
9 clarification, yes.

10 BY MR. NICHOLAS:

11 Q. For the distributors?

12 A. For all registrants who order, yeah, and
13 distribute.

14 Q. And is that work -- well, do you know
15 whether that work is still ongoing?

16 A. I don't know for certain.

17 Q. And when I say that work, I mean the work
18 to revise the regulation. You don't know whether
19 that's --

20 A. As of March of 2018, it was. I haven't
21 had a conversation with anybody about it since then
22 at DEA.

23 Q. Let's go to the next exhibit. I've just
24 been told to make the same speech, so I'm going to
25 do it. This next document, which we can mark as

1 Ashley 13, is a document which -- another document
2 which the government told us this morning they
3 would like to claw back. We had a productive and
4 amicable discussion about how we might be able to
5 use the document in a redacted form. We do reserve
6 our rights to discuss it more later, but we will
7 use the redacted document for purposes of this
8 deposition.

9 MR. SHKOLNIK: For the record, I would --
10 plaintiff was not included in the amicable
11 discussion as to what was the agreed redaction. So
12 I think that's something at the lunch break we
13 should be talking about. Defense counsel may be
14 happy with those areas redacted, but I think I
15 should have been included in that conversation.

16 (Whereupon, ASHLEY Deposition
17 Exhibit No. 13 was marked for
18 identification.)

19 BY MR. NICHOLAS:

20 Q. Can you take a look at Ashley 13. It is a
21 one-page document, and it is an e-mail to you,
22 Ms. Ashley, from Mr. Milione dated November 27,
23 2016. The subject is forward, colon, regs, and it
24 encloses or it forwards a message from Mr. Milione
25 to Chuck Rosenberg with a CC to BenAry, Michael

1 BenAry and with a CC to Louis Milione. He CC'd
2 himself, I guess, and a CC also to Robert
3 Patterson.

4 So I should ask you, for the record, who
5 Chuck Rosenberg is?

6 A. Chuck Rosenberg was the acting
7 administrator for DEA at the time.

8 Q. So he was Mr. Milione's boss?

9 A. Yes.

10 Q. Mr. Milione's e-mail to Mr. Rosenberg says
11 we need to put together a draft of the suspicious
12 order regs, which will take some time and then get
13 that to OLP when that draft is in pretty good
14 shape. We've been getting general input from
15 industry and the field and hope to put a draft reg
16 together that is clearer and helps distributors be
17 more effective. Our reg drafters, slash, policy
18 analysts and diversion are a bit crushed right now
19 with other priority regs.

20 We are in the process of hiring additional
21 reg drafters, slash, policy analysts, which should
22 alleviate some of the workload issues. My goal is
23 to get a draft suspicious order reg done internally
24 early in 2017. Happy to talk if you want to
25 tonight or whenever is convenient.

1 Do you know from your own personal
2 knowledge whether a draft suspicious order reg was
3 done internally early in 2017?

4 A. There was a draft in 2017. I don't know
5 how early it was, but there was a draft.

6 Q. Did you see the draft?

7 A. Yes.

8 Q. Did you comment on the draft?

9 A. Yes.

10 Q. Was the draft revised after that?

11 A. Oh, yes.

12 Q. When is the last time you saw a draft of
13 this proposed new reg or revised reg?

14 A. I would be guessing. It would be early
15 2018.

16 Q. And do you know -- we've covered this, but
17 I want to make sure for the record it's clear. Do
18 you know what has become of that draft, the most
19 recent draft? Do you know what the status is?

20 A. I do not.

21 Q. Okay. Now, Mr. Milione, in forwarding
22 this message to you, says FYI, period, will need to
23 make this a priority in the new year, period. Not
24 sure why he questioned -- I think maybe it's a
25 typo. It means why the question from Chuck and

1 hope to discuss with him to find out.

2 To your knowledge, did -- strike that.

3 Do you know why in your personal
4 interactions with Mr. Milione or your job, you
5 know, as you understood it, why Mr. Milione was
6 telling you that we'll need to make this a priority
7 in the new year?

8 A. Do I know why he phrased it that way? It
9 was an important issue for us.

10 Q. Why was it an important issue for you?

11 A. Because we had been engaging with
12 registrants, and they were telling us that they
13 needed or wanted more clarification.

14 Q. Did DEA make this a priority in the new
15 year?

16 MS. BACCHUS: Objection. Form. Scope.

17 BY MR. NICHOLAS:

18 Q. If you know. In your personal knowledge,
19 did DEA make this a priority in the new year?

20 A. In my personal knowledge, yes.

21 Q. But the reg wasn't completed; is that
22 correct?

23 A. It was not completed.

24 Q. And evidently it's still not completed; is
25 that correct?

1 MS. BACCHUS: Objection.

2 THE WITNESS: I don't know.

3 BY MR. NICHOLAS:

4 Q. Now, you said that this was important and
5 appropriately a priority because the registrants
6 were seeking further -- you know, were seeking it;
7 is that right?

8 A. Yes.

9 MR. SHKOLNIK: Objection to form.

10 BY MR. NICHOLAS:

11 Q. And is it right that the reason you cared
12 that the registrants were seeking it is that you
13 wanted to put them in a position to be more
14 effective?

15 MR. SHKOLNIK: Objection. Form.

16 MS. BACCHUS: Objection. Form.

17 MR. SHKOLNIK: DEA's position? Her personal
18 opinion?

19 MR. NICHOLAS: I'm asking her personal opinion.

20 MR. SHKOLNIK: Okay. Then the question should
21 so state that.

22 MR. NICHOLAS: Okay. It's stated.

23 THE WITNESS: In my personal opinion and
24 engagements with the registrants, I felt that we
25 weren't understanding each other. I was clear on

1 the regulation, and they said they were not. So we
2 needed -- we needed to meet and resolve it. So
3 that's why it was a priority for me.

4 BY MR. NICHOLAS:

5 Q. Do you recall attending a meeting on
6 August 30, 2017 with HDA?

7 A. Not specifically.

8 Q. The meeting would have been or was at the
9 invitation of the DEA. Patrick Kelly and Ruth
10 Miller of HDA met with DEA diversion control
11 division staff. Does this ring any bells? I'm
12 just reading it.

13 A. It's not. It's not, but it's not unusual.

14 Q. Okay. Well, let's just mark this as the
15 next exhibit, Ashley 14.

16 (Whereupon, ASHLEY Deposition
17 Exhibit No. 14 was marked for
18 identification.)

19 BY MR. NICHOLAS:

20 Q. So what I'm giving you or what I've given
21 you is an e-mail from Ruth Miller of HDA. It was
22 sent on August 30, 2017 to regulatory affairs
23 committee, legal committee. So this may be an
24 internal HDA document that was produced in this
25 litigation, and the reason I'm asking you about it,

1 in part, is because you're mentioned in the e-mail,
2 and you're mentioned as having attended briefly
3 portions of the meeting.

4 So taking a look at this, I guess I'll
5 start out by asking you whether this refreshes your
6 memory as to --

7 A. Yes.

8 Q. It does?

9 A. Yes.

10 Q. What do you remember about this meeting?

11 A. What I remember is we were working with
12 DOJ on the Reform Regulation Reduction Act, and so
13 part of that was speaking with industry about the
14 regulations and trying to get their assessment on
15 if they were to -- if the regulations were, you
16 know, too burdensome. So we had a series of
17 conversations with the different registrant
18 communities about that subject.

19 Q. And the regulation that was being
20 discussed here was the regulation we've been
21 talking about today; is that right?

22 A. No. It was all DEA regulations.

23 Q. Okay. Go to -- well, this document says
24 that acting assistant administrator, Demetra Ashley
25 attended briefly, but the core of the conversation

1 was with Mike Lewis, chief of the regulatory
2 drafting section and two other staff.

3 So Mr. Lewis, did you know Mr. Lewis?

4 A. Yes.

5 Q. He was the person who drafted the regs?

6 A. He was the section chief of the regulatory
7 drafting section, so he had a staff of about
8 20 individuals that drafted regulations.

9 MR. SHKOLNIK: I'm sorry. Which paragraph are
10 you on?

11 MR. NICHOLAS: Paragraph 1. I just read from
12 Paragraph 1.

13 BY MR. NICHOLAS:

14 Q. But now I'm going to go down to the second
15 to the last paragraph, which is headed gray is good
16 in quotes and accountability in quotes. The
17 paragraph reads, and this is, again, an HDA person,
18 Ruth Miller reporting on the meeting, we gained a
19 little insight into Mr. Lewis's perspectives about
20 how regulations should be written. While he
21 expressed concern that some of the DEA regulations
22 have remained unchanged since 1971, he also
23 expressed that based on his experience in the field
24 for DEA, quote, gray is good, unquote, meaning that
25 overly defining requirements can create its own

1 problems.

2 HDA pointed out that while flexibility is
3 necessary, it is also essential that the agency
4 establish parameters so that the registrants can
5 understand when they have strayed outside.

6 Mr. Lewis also expressed his view that the agency
7 should clearly convey each -- should clearly convey
8 each registrant's, quote, accountability, unquote,
9 so that registrants understand and can accept their
10 responsibilities.

11 I was interested in this phrase gray is
12 good. In your experience at DEA and thinking in
13 particular about the regulation we've been talking
14 about, the suspicious order monitoring
15 regulation --

16 MR. SHKOLNIK: Objection.

17 BY MR. NICHOLAS:

18 Q. -- is gray is good an accurate way to
19 describe the approach that the agency has taken to
20 explaining registrants' obligations under the CSA
21 relating to the distribution of controlled
22 substances?

23 MR. SHKOLNIK: Objection.

24 MS. BACCHUS: Objection. Calls for --

25 MR. SHKOLNIK: Is it her opinion, the agency's

1 opinion, or is it just someone's interpretation of
2 the HDA's opinion?

3 BY MR. NICHOLAS:

4 Q. Let me ask you your opinion. Let me just
5 talk to you about this, you, personally, all right?
6 Do you have a reaction -- do you have a view as to
7 whether gray is good is a good way to go about
8 drafting the regulations --

9 MS. BACCHUS: Same objection.

10 MR. SHKOLNIK: Objection.

11 BY MR. NICHOLAS:

12 Q. -- in question?

13 A. You know, I don't know what he's talking
14 about. Reaction? When I read gray is good, I
15 thought about the gray market, the retail
16 pharmacies that are not part of the chains. That's
17 what I thought about when I saw it. So I wasn't
18 thinking gray as in vague. So I don't know what he
19 meant.

20 Q. Okay.

21 MR. NICHOLAS: Let's go off the record.

22 THE VIDEOGRAPHER: We're off the record at
23 12:35 p.m.

24 (Whereupon, a discussion was
25 had off the record.)

1 (Whereupon, ASHLEY Deposition
2 Exhibit No. 15 and 16 were
3 marked for identification.)

4 THE VIDEOGRAPHER: We are back on the record at
5 12:37 p.m.

6 BY MR. NICHOLAS:

7 Q. So I've just handed out -- I've just
8 marked two exhibits, Ashley 15 and Ashley 16.
9 Ashley 15 is a letter from Kevin Nicholson, vice
10 president of public policy and regulatory affairs
11 of the National Association of Chain Drug Stores.
12 Is that the drug stores trade association?

13 A. Yes.

14 Q. And it's a letter to you dated
15 February 6th of 2018?

16 A. Yes.

17 Q. And then the next letter I gave you is
18 your answer your response to that letter, which is
19 dated -- maybe, maybe not. Let's see. Is the
20 DEA's response. The letter was written to you, but
21 the DEA responded. James Arnold responded to
22 Mr. Nicholson. Do you see that?

23 A. Yes.

24 Q. So do you recall receiving this letter
25 from NACDS?

1 A. Not specifically, no.

2 Q. Okay. Can you take a look at the letter.

3 You see that the letter in the first paragraph

4 references a court decision called Masters

5 Pharmaceutical, Inc. v. Drug Enforcement

6 Administration, parentheses, close quote, Masters?

7 A. Yes.

8 Q. You've heard of the Masters decision?

9 A. Yes.

10 Q. And you see that the NACDS was asking for

11 DEA to promulgate regulations to affected

12 registrants regarding their suspicious order

13 monitoring regulatory obligations in light of the

14 Masters decision. Do you see that?

15 A. Yes.

16 Q. And in the letter, Mr. Nicholson says we

17 are concerned -- this is the last paragraph of the

18 first page. We are concerned that the D.C. Circuit

19 may have interpreted the suspicious reporting

20 requirement under 21 CFR Section 13.01.74(b)

21 differently than DEA has interpreted the regulation

22 in the past or intended to do so in the future.

23 Moreover, DEA field division offices across the

24 country may each have their own interpretation of

25 the Masters decision, which could significantly

1 affect enforcement of this regulation.

2 Do you see that?

3 A. Yes.

4 Q. And then on the second page, Mr. Nicholson
5 submits two specific questions. His first question
6 is, one, whether all orders identified as orders of
7 interest must now be reported to DEA as suspicious,
8 and two, is there a middle ground the DEA perceives
9 may exist that permits both statistically-driven
10 threshold systems and order of interest systems
11 such that registrants operating the latter system
12 need not prematurely or automatically deem an order
13 as suspicious when the order is merely flagged for
14 further review.

15 And then in the last paragraph,
16 Mr. Nicholson asks that the DEA address these
17 questions so that Mr. Nicholson, in effect, is
18 asking for the answer to those two questions, and
19 then he's also asking for the promulgation of
20 regulations in light of Masters. He's got
21 specific -- this is a letter which is asking for
22 pretty specific things, correct?

23 MS. BACCHUS: Objection. The letter speaks for
24 itself.

25 THE WITNESS: I agree that they're two

1 questions.

2 BY MR. NICHOLAS:

3 Q. And they're specific?

4 MR. SHKOLNIK: Objection.

5 BY MR. NICHOLAS:

6 Q. They're specific questions?

7 MR. SHKOLNIK: Objection to form.

8 THE WITNESS: I agree that there are two
9 specific questions on this letter.

10 BY MR. NICHOLAS:

11 Q. And do you also agree that asking for the
12 DEA to promulgate regulations to affected
13 registrants regarding their suspicious order
14 monitoring regulations, regulatory obligations in
15 light of Masters, that's also a clear request.
16 It's a specific request?

17 MR. SHKOLNIK: Objection to form.

18 MS. BACCHUS: Objection.

19 THE WITNESS: Where did you just read from?

20 BY MR. NICHOLAS:

21 Q. The first paragraph.

22 A. Yes, that's a request.

23 Q. Okay. Now, what did you do with the
24 letter when you received it?

25 A. I don't recall.

1 Q. Did you talk to -- do you recall whether
2 you called Mr. Nicholson?

3 A. No.

4 Q. Have you ever spoken to him before?

5 A. Yes.

6 Q. You knew him previously from --

7 A. Yes.

8 Q. -- dealing with this trade organization?

9 A. Yes.

10 Q. Do you recall whether you did anything
11 related to responding to this letter?

12 A. I don't recall.

13 Q. Do you recall speaking with anyone about
14 this letter at any time?

15 A. I -- I don't remember.

16 Q. Okay. Let's look at Mr. -- let's look at
17 the response that Mr. Nicholson received.

18 A. Okay.

19 Q. You can take a minute to look at it.

20 A. Okay.

21 Q. Now, you've just read the response from
22 Mr. Arnold. Who is Mr. Arnold, James Arnold who
23 responded to this letter that was written to you?

24 A. Jim Arnold, at the time, was the section
25 chief of the policy and liaison section.

1 Q. Do you have any recollection as to how it
2 came to be that Mr. Arnold is the person who
3 responded to this letter?

4 A. Yes. I mean, recollection of it, no.
5 It's just standard because he's the section chief
6 of the section that drafts responses.

7 Q. Okay. Do you recall reviewing the
8 response before it went out?

9 A. No. I was retired by that time.

10 Q. Okay. Reading the response, does the
11 response provide an answer to either question that
12 Mr. Nicholson asked?

13 MR. SHKOLNIK: Objection. Outside the scope.
14 The witness wasn't there. It wouldn't be from her
15 own knowledge of what was going on.

16 MS. BACCHUS: Same objection. She can only
17 testify to what's stated in the letter itself. I
18 think everybody can read it and interpret it for
19 themselves.

20 MR. NICHOLAS: I'm only asking her to testify
21 about what's stated in the letter. I agree.

22 BY MR. NICHOLAS:

23 Q. Does the letter -- does the letter written
24 back to Mr. Nicholson answer the two questions that
25 were posed?

1 A. Not specifically.

2 Q. Does the letter mention Masters at all,
3 the letter back?

4 A. It does not.

5 MS. BACCHUS: Same objection.

6 MR. SHKOLNIK: Objection. Outside the scope of
7 this witness.

8 BY MR. NICHOLAS:

9 Q. Now, on the first page of the letter,
10 Mr. Arnold does on the last -- take a look at the
11 last paragraph that begins with the word finally,
12 and it says finally, the DEA has proposed to revise
13 its regulations relating to suspicious orders of
14 controlled substances. The proposed rule defines
15 the term suspicious order and specifies the
16 procedures a registrant must follow upon receiving
17 such orders.

18 Do you see that?

19 A. Yes.

20 Q. So Mr. Arnold was telling Mr. Nicholson
21 that in June of 2018, there was a proposed rule
22 being discussed at DEA that would define the term
23 suspicious order and specify the procedures a
24 registrant must follow upon receiving such orders,
25 right?

1 MR. SHKOLNIK: Objection.

2 MS. BACCHUS: Objection. Outside of the scope.

3 BY MR. NICHOLAS:

4 Q. That's what he wrote?

5 MR. SHKOLNIK: Objection. This witness wasn't
6 at DEA, and you're asking for interpretations.

7 MR. NICHOLAS: No, I'm not. I'm just asking
8 what the letter says.

9 MR. SHKOLNIK: And she wasn't there. She's
10 here as a witness.

11 MR. NICHOLAS: I'm just asking her to read the
12 letter.

13 BY MR. NICHOLAS:

14 Q. Go ahead. You can answer.

15 MS. BACCHUS: Same objection.

16 THE WITNESS: If you're reading straight from
17 the letter, yeah, I read the same thing you do.

18 BY MR. NICHOLAS:

19 Q. Okay. And were you aware at -- were you
20 aware of the fact at any point of the fact that the
21 proposed rule that was being discussed at DEA when
22 you were still there would define the term
23 suspicious order and specify the procedures a
24 registrant must follow upon receiving such orders?

25 A. I wouldn't agree to that language, no.

1 Q. Well, I'm saying were you aware that this
2 was what the proposed rule was going to do?

3 MR. SHKOLNIK: Objection. Asked and answered.
4 She disagreed with you.

5 MR. NICHOLAS: I didn't understand the answer.
6 BY MR. NICHOLAS:

7 Q. Go ahead.

8 A. I was aware that DEA was drafting a new
9 regulation. Defining the term, I wouldn't -- I
10 would say further defined.

11 Q. Further defined. So your recollection is
12 that the new proposed rule was going to further
13 define suspicious order?

14 A. Existing.

15 MS. BACCHUS: I'm going to object to discussing
16 what the proposed rule was going to do or not. It
17 was a draft.

18 THE WITNESS: Right. That's true. It was a
19 draft.

20 BY MR. NICHOLAS:

21 Q. And it's still a draft because nothing has
22 come out yet?

23 MS. BACCHUS: Objection. Asked and answered.

24 MR. SHKOLNIK: Objection. This is going into
25 the workings of the DEA --

1 THE WITNESS: I don't know.

2 MR. SHKOLNIK: -- that we're not supposed to be
3 covering.

4 MR. NICHOLAS: I think we'll probably -- give
5 me one second. We may be ready for our lunch
6 break. Let's look at one more document because
7 it's referenced in the document we just looked at.
8 This is Ashley 17.

9 (Whereupon, ASHLEY Deposition
10 Exhibit No. 17 was marked for
11 identification.)

12 BY MR. NICHOLAS:

13 Q. Now, if you take a look at Ashley 17 and
14 then look back at Ashley 16, and in that paragraph
15 you were looking at at the bottom of the page where
16 Mr. Arnold of the DEA is writing back to
17 Mr. Nicholson and he's saying, and we just read
18 this in the final paragraph of the first page,
19 finally, the DEA is proposed to revise its
20 regulations relating to suspicious orders of
21 controlled substances. The proposed rule defines
22 the term suspicious order and specifies the
23 procedures a registrant must follow upon receiving
24 such orders. You can monitor the progress of the
25 suspicious orders of controlled substances proposed

1 rule on the unified agenda located at
2 www.regulations.gov. The above-stated proposed
3 rule has been assigned regulatory identification
4 number, parentheses, RIN 1117-AB47.

5 Do you see that?

6 A. Yes.

7 Q. So it turns out you can actually go to the
8 internet and track what's going on with proposed
9 rules at the DEA, correct?

10 A. Yes.

11 Q. Okay. And the document I just gave you,
12 the new one, which is Ashley 17, is a snapshot of
13 that web page where you can go to track the
14 proposed rule. Do you see that?

15 A. Yes.

16 Q. And it has the same RIN number. If you
17 look at the RIN number, RIN, it says 1117-AB47.

18 Do you see that?

19 A. Yes.

20 Q. Okay. And it says -- so we're talking
21 about the proposed rule in question, the proposed
22 rule that was having to do with suspicious order
23 ordering monitoring programs, correct?

24 A. Yes.

25 Q. And it says on publication ID spring 2018.

1 Do you see that?

2 A. Yes.

3 Q. So I will confess I don't know whether
4 that means that this document was printed out, a
5 snapshot as of -- I take it back. I do know. If
6 you look at the date in the top left-hand corner of
7 this document, it says 3/8/2019.

8 So this is a snapshot of what was going on
9 as of March 8, 2019.

10 A. Okay.

11 Q. And it says abstract, colon, the Drug
12 Enforcement Administration is proposing to revise
13 its regulations relating to suspicious orders of
14 controlled substances. The proposed rule defines
15 the term suspicious order and specifies the
16 procedures a registrant must follow upon receiving
17 such orders.

18 Do you see that?

19 A. Yes.

20 Q. And do you see that underneath that, it
21 says priority, colon, and then it says substantive,
22 comma, nonsignificant? Do you see that?

23 A. I see that.

24 Q. Okay. Based on your work -- based on your
25 experience when you were at the DEA, do you know

1 what that meant, priority substantive, comma,
2 nonsignificant?

3 A. Based on my experience, when it is noted
4 nonsignificant, it was the emphasis on, say, the
5 urgency of the public interest. Like if there were
6 a rule that needed to go in place immediately
7 because of some threat to the public, it would be
8 deemed significant. If it's nonsignificant, it's
9 just a regular drafting that we need to get done.
10 Not that it's not a priority, but it's not as
11 urgent as some others may be.

12 Q. We have reviewed documents today this
13 morning that show that HDA was asking for revision
14 of the regulation in question, the regulation
15 pertaining to suspicious order monitoring all the
16 way back to 2010. Do you remember that?

17 A. Yes.

18 Q. And here as of 2019, no such regulation,
19 revised regulation has been forthcoming; is that
20 correct?

21 MS. BACCHUS: Objection to form. This is if
22 you know.

23 MR. SHKOLNIK: Objection.

24 BY MR. NICHOLAS:

25 Q. Is that correct?

1 A. To my knowledge, there's not a new
2 regulation.

3 MR. NICHOLAS: Okay. We can take a lunch
4 break.

5 THE VIDEOGRAPHER: We are off the record at
6 12:56 p.m.

7 (Whereupon, a lunch break was
8 taken.)

9 THE VIDEOGRAPHER: We are back on the record at
10 1:53 p.m.

11 MR. NICHOLAS: I'd like to mark the next
12 exhibit, please, which I think may be Ashley 18.

13 (Whereupon, ASHLEY Deposition
14 Exhibit No. 18 was marked for
15 identification.)

16 BY MR. NICHOLAS:

17 Q. Ms. Ashley, good afternoon. I've handed
18 you Ashley 18, which is -- which shows two e-mails.
19 The most recent e-mail is an e-mail from Matthew
20 Strait to Mary Brandenberger at the DEA as well as
21 Katherine Pfaff at the DEA and Barbara Carreno at
22 the DEA with a CC to Sean Mitchell at the DEA, and
23 it encloses a -- it encloses an e-mail that
24 Mr. Strait sent to you and several other people,
25 which, you know, attaches a press announcement

1 that, I believe, either -- may have come from the
2 DEA itself.

3 So let's take this from the bottom. I
4 don't need to ask you a lot of questions about
5 this, but do you recall receiving -- well, first of
6 all, who is Matthew Strait?

7 A. Matthew Strait at the time was -- let me
8 see, February of '18. Yeah, he reported directly
9 to me. He was more of the public information
10 person for diversion.

11 Q. And he was sending you this press release?

12 A. Yes.

13 Q. And the press release is about the DEA
14 launching a new tool to assist drug manufacturers
15 and distributors with their regulatory obligations
16 under the Controlled Substances Act. Do you see
17 that in the first sentence?

18 A. Yes.

19 Q. And that new tool had to do with making
20 ARCOS information available to the distributors; is
21 that right?

22 A. Correct.

23 MS. BACCHUS: Objection. Beyond the scope of
24 what she's authorized to testify to.

25

1 BY MR. NICHOLAS:

2 Q. Well, the document --

3 MR. NICHOLAS: Are you instructing her not to
4 answer?

5 MS. BACCHUS: I am. If you're going to ask her
6 any questions about the ARCOS system, yes.

7 BY MR. NICHOLAS:

8 Q. Well, let's take it one question at a
9 time. So far I think what I've asked you is
10 whether the new tool or the new thing that was
11 released was -- to the distributors was access to
12 certain ARCOS information, correct?

13 A. Yes.

14 Q. And I think I can ask you whether that is,
15 in fact, what happened in 2018, that the DEA worked
16 out a way to have more -- to have some ARCOS
17 information released to the distributors?

18 MS. BACCHUS: I'm going to object to the form
19 of the question. If you know.

20 MR. SHKOLNIK: Objection. Outside the scope.

21 BY MR. NICHOLAS:

22 Q. Go ahead.

23 A. This notifications states that it's
24 providing access to more information to
25 registrants, yes, it does.

1 Q. More information from the ARCOS data?

2 A. From ARCOS data.

3 Q. Can you just explain what -- to the best
4 of your personal knowledge, what it was that was
5 being made available that previously had not been
6 made available to distributors?

7 MR. SHKOLNIK: Objection. We were given
8 limitations on this witness to talk about anything
9 regarding ARCOS, and I think this is far field.
10 You said it's just about this e-mail and
11 notification. Now we're going into the details of
12 ARCOS.

13 MR. NICHOLAS: Let's just -- we can keep the
14 clock running, but let's just go off the record for
15 one second. You can run the clock if you want.
16 Okay. We can go back on the record.

17 BY MR. NICHOLAS:

18 Q. This press release was issued when you
19 were still with the DEA; is that right?

20 A. Yes.

21 Q. And it pertains to information being made
22 available to manufacturers and distributors; is
23 that right?

24 A. Yes.

25 Q. And you were with the Office of Diversion

1 Control during this time period; is that right?

2 A. Yes.

3 Q. And you were communicating with
4 manufacturers and distributors about issues related
5 to their respective programs; is that correct?

6 A. Yes.

7 Q. And you were communicating with
8 manufacturers and distributors with regard to
9 issues relating to combatting the ongoing opioid
10 crisis; is that correct?

11 A. Yes.

12 Q. Okay. And this new information that was
13 being made available was a tool to assist the
14 manufacturers and the distributors in helping to
15 combat the ongoing opioid crisis; is that correct?

16 A. Yes.

17 Q. And you had discussed -- is it correct
18 that you had discussed this new tool with the
19 manufacturers and the distributors?

20 A. Not this tool specifically, no.

21 Q. You're saying you never talked to
22 manufacturers and distributors about ARCOS data?

23 MR. SHKOLNIK: Objection.

24 THE WITNESS: Yes, I have.

25

1 BY MR. NICHOLAS:

2 Q. You have?

3 A. Yes. I'm thinking technically of the tool
4 itself, the database.

5 Q. Okay. So you have communicated with
6 manufacturers and distributors over the years about
7 the ARCOS database; is that right?

8 A. Yes.

9 Q. And in those communications, they've
10 expressed a desire to have access to the ARCOS
11 database; is that right?

12 A. Yes.

13 MR. SHKOLNIK: Objection to form.

14 THE WITNESS: Yes.

15 BY MR. NICHOLAS:

16 Q. And until this 2018 time period, they did
17 not have access to the ARCOS database; is that
18 right?

19 A. They had access to some information, not
20 all that they wanted, but yes, they did have some.

21 Q. Very limited; is that correct?

22 A. I wouldn't describe it as very limited. I
23 wouldn't describe it that way.

24 Q. But what was released in 2018 provided
25 them with more information than they had had

1 previously, correct?

2 MR. SHKOLNIK: Objection. Outside the scope --

3 BY MR. NICHOLAS:

4 Q. You can go ahead.

5 MR. SHKOLNIK: -- of the Touhy.

6 THE WITNESS: That's correct.

7 BY MR. NICHOLAS:

8 Q. I would like to go ahead and inquire into
9 this, and I'm just going to direct you to -- I'm
10 now -- I'm talking to your counsel.

11 MR. NICHOLAS: If you look at your letter, the
12 Touhy letter to Ms. Ashley No. 5, your personal
13 recollection regarding your interactions with
14 manufacturers and distributors of opioids during
15 your tenure at the Office of Diversion Control --

16 MS. BACCHUS: Yes.

17 MR. NICHOLAS: -- I think the questions I just
18 asked make it pretty clear that Ms. Ashley was
19 talking to -- was communicating with manufacturers
20 and distributors while she was in the job described
21 here about ARCOS -- about the ARCOS data and
22 specifically the request for more -- for access to
23 more of the ARCOS data so that they could -- so
24 they could enhance their ability to work with the
25 requirements, the suspicious order monitoring

1 requirements.

2 MS. BACCHUS: The issue, as I see it, in terms
3 of what she's authorized to testify regarding, she
4 can talk about that they wanted information from
5 the ARCOS, but she cannot discuss what's in the
6 ARCOS database, why they weren't given information
7 from the ARCOS database, that type of information.

8 MR. NICHOLAS: I won't ask her why they weren't
9 given it previously. I would like to be able to
10 ask her just rudimentary questions about what's in
11 it, what's the information. I'm not going to ask
12 her why over the years you refused to or you
13 declined to provide that access, but I do want to
14 be able to say what's the data, what's in it.

15 MS. BACCHUS: I don't think she can testify to
16 that. To the extent what was in it was
17 communicated to the registrants, she can talk about
18 that, but in terms of what other information, she
19 can not speak to.

20 MR. NICHOLAS: Okay. Then I'm going to take it
21 one question at time.

22 MS. BACCHUS: All right.

23 MR. NICHOLAS: And let me try it this way.

24 BY MR. NICHOLAS:

25 Q. In order to try to abide by your counsel's

1 limiting instruction, I'm going to ask you
2 questions where -- if this is information that was
3 discussed with or shared with the manufacturers and
4 distributors between you and them, you and they, I
5 would like you to answer the question.

6 MR. SHKOLNIK: Objection to form.

7 MR. NICHOLAS: Object to what?

8 MR. SHKOLNIK: I thought that was a question.
9 You wanted her to answer the last question.

10 MR. NICHOLAS: I have no idea what you're
11 saying.

12 MR. SHKOLNIK: You had a question pending and
13 now --

14 MR. NICHOLAS: She and I understood each other,
15 so that's probably more important.

16 BY MR. NICHOLAS:

17 Q. Ms. Ashley, are you familiar with ARCOS
18 data?

19 A. Yes.

20 Q. Okay. And have you seen ARCOS reports
21 before?

22 A. Yes.

23 MR. SHKOLNIK: Objection. We were given
24 instructions to limit -- we could not ask about
25 ARCOS and what's in it and what is available, and

1 we did not have the opportunity to prepare for that
2 because of the limitations placed by the
3 government. And now to let the distributor counsel
4 inquire into the specifics, have you seen what's in
5 ARCOS before, are you familiar with the data,
6 that's going into the heart of it. And we're
7 asking for instruction that the witness not be
8 allowed or that we come back on another day for
9 this issue where we've had an opportunity to
10 prepare for it.

11 MR. NICHOLAS: Okay. I'm going to keep going.
12 I think --

13 MS. BACCHUS: I'm sorry. Can I, for the
14 record, just say that the witness is authorized to
15 answer as to what she communicated to the
16 registrants about ARCOS, but she cannot discuss the
17 specifics of the information that is in ARCOS
18 unless it is something that she shared specifically
19 with the registrants.

20 BY MR. NICHOLAS:

21 Q. Did you share with the registrants or with
22 registrants at any time the fact that ARCOS data
23 includes in it the name of the distributor?

24 MR. SHKOLNIK: Objection.

25 THE WITNESS: The name of the distributor that

1 I'm speaking to or in general?

2 BY MR. NICHOLAS:

3 Q. No.

4 A. The name of any distributor?

5 Q. Yeah. Does ARCOS data report --

6 MR. SHKOLNIK: Same objection.

7 BY MR. NICHOLAS:

8 Q. -- the name of the distributor? Did you
9 share that information with the distributors?

10 A. It's likely, yes.

11 Q. Did you share with the distributors the
12 fact that ARCOS data contains within it the name of
13 the pharmacy at issue in question?

14 A. Yes.

15 MR. SHKOLNIK: Objection.

16 MS. BACCHUS: Objection. Vague.

17 MR. NICHOLAS: She said yes.

18 BY MR. NICHOLAS:

19 Q. Did you share with -- did you share with
20 the distributors the fact that ARCOS data contains
21 within it the date of the sale being reported?

22 MR. SHKOLNIK: Objection.

23 THE WITNESS: So I guess I have a question. In
24 the course of a discussion, did we talk about those
25 things?

1 BY MR. NICHOLAS:

2 Q. Yeah.

3 A. Yes.

4 Q. In the course of a discussion or
5 otherwise, did you share with the manufacturers and
6 distributors or one or the other or both the fact
7 that ARCOS data contains the type of opioid that's
8 being distributed?

9 MR. SHKOLNIK: Objection. Same objection.

10 THE WITNESS: Yes.

11 BY MR. NICHOLAS:

12 Q. Did you share with manufacturers and
13 distributors in the course of discussions or
14 conversations or communications the fact that ARCOS
15 data contains within it the strength of the opioid
16 being distributed?

17 MR. SHKOLNIK: Objection. What was the purpose
18 of providing us a limitation?

19 THE WITNESS: I can't say specifically that
20 thing, but maybe.

21 BY MR. NICHOLAS:

22 Q. And lastly, did you share with the
23 registrants with whom you had conversations over
24 the years about ARCOS data the fact that ARCOS data
25 contained the amount of opioids distributed that

1 were being --

2 MR. SHKOLNIK: Objection. Outside the scope.

3 THE WITNESS: I would say yes.

4 BY MR. NICHOLAS:

5 Q. And based on your knowledge and your
6 experience in your job, various jobs, prior to
7 2018, this information that we just went through
8 was only available to the DEA; is that correct?

9 MR. SHKOLNIK: Objection.

10 MS. BACCHUS: Objection. Form.

11 THE WITNESS: I would say no.

12 BY MR. NICHOLAS:

13 Q. Is it correct that it was all available to
14 the DEA?

15 MS. BACCHUS: Objection. Vague.

16 MR. SHKOLNIK: Objection. Outside.

17 THE WITNESS: This information?

18 BY MR. NICHOLAS:

19 Q. Yes.

20 A. Yes.

21 Q. Okay. And the thing I'll ask you about
22 this document, Ashley 18, in the press release from
23 the DEA, there's a statement which reads as
24 follows: It's a little more than halfway down the
25 page. It starts with the word manufacturer, and

1 the sentence reads manufacturers and distributors
2 have consistently expressed a desire for assistance
3 from DEA in fulfilling these obligations and have
4 requested ARCOS information to help them make
5 informed decisions about whether new customers are
6 purchasing excessive quantities of controlled
7 substances.

8 Based on your experience working at the
9 DEA; is that a true statement?

10 A. Yes, that is.

11 Q. And that is something which the
12 distributors have been asking for since at least
13 2010, correct?

14 MR. SHKOLNIK: Objection.

15 MS. BACCHUS: Objection to form of the
16 question.

17 THE WITNESS: In my personal experience,
18 they've asked for it.

19 BY MR. NICHOLAS:

20 Q. You don't want me to go back and do the
21 same segments of the questions I asked before, do
22 you?

23 All right. Just two more areas, and then
24 I think we're going to be done.

25 Are you familiar with the Ensuring Patient

1 Access and Effective Drug Enforcement Act?

2 A. Yes.

3 Q. Do you recall or know that the act was
4 signed into law in April of 2016?

5 A. Yes, I recall.

6 Q. Do you recall -- we talked before about
7 how you had the experience of being able to testify
8 before Congress, right?

9 A. Yes.

10 Q. Do you recall testifying before Congress
11 and being asked some questions by Senator Cruz
12 having to do with the Ensuring Patient Access and
13 Effective Drug Enforcement Act?

14 A. I remember him asking questions, not
15 specifically what the question was.

16 Q. Do you remember -- I'm going to read you
17 his question and your answer. I tell you what.
18 Let's introduce your testimony for -- just so we
19 have it on record. I'm not going to make us look
20 through it, okay, but let's do it just so we have a
21 complete record. Next exhibit is Ashley 19.

22 (Whereupon, ASHLEY Deposition
23 Exhibit No. 19 was marked for
24 identification.)
25

1 BY MR. NICHOLAS:

2 Q. You can just take a look through it and
3 tell me if it appears to be an accurate transcript
4 of your testimony. Page 8 is where you're
5 introduced, by the way, and then it proceeds from
6 there.

7 A. Yes, this appears to be a copy of my
8 testimony.

9 Q. Okay. I'm going to take the liberty of
10 reading a few questions and answers. I have the
11 page numbers, but I'm just going to read them to
12 you. If you remember them, great. If not, just
13 tell me, okay?

14 A. Okay.

15 Q. So on Page 25 of this document, Ms. --
16 Senator Cruz --

17 MS. BACCHUS: Can you give her a minute to get
18 to the page?

19 THE WITNESS: I'm sorry.

20 MR. NICHOLAS: Absolutely.

21 BY MR. NICHOLAS:

22 Q. You can look if you want. It's Page 25.
23 It's about two-thirds of the way down or a little
24 more. Right after you say yes, sir, there's a
25 question from Senator Cruz, and the question is and

1 the DEA supported the legislation and the version
2 that actually passed, question mark, and your
3 answer was yes, sir.

4 Do you see that?

5 MR. SHKOLNIK: Objection.

6 MS. BACCHUS: Objection.

7 MR. SHKOLNIK: Objection. Improper use of
8 prior testimony.

9 MS. BACCHUS: Can I get a reference to what
10 legislation we're talking about?

11 MR. NICHOLAS: We're talking about the Ensuring
12 Patient Access and Effective Drug Enforcement Act.

13 MR. SHKOLNIK: Objection to form.

14 BY MR. NICHOLAS:

15 Q. My only question is do you recall being
16 asked this question and giving this answer?

17 A. Do I recall --

18 MR. SHKOLNIK: Objection. Improper use of
19 prior testimony.

20 THE WITNESS: -- being asked specifically? No.
21 I recall that Senator Cruz did question me. I
22 don't remember the questions.

23 BY MR. NICHOLAS:

24 Q. Okay. Do you remember that he -- I'll try
25 to do this differently then. Do you remember that

1 he invited you, on behalf of the DEA, to submit any
2 additional language or changes you wanted to make
3 to the proposed legislation?

4 A. Not specifically Senator Cruz, but yeah.

5 Q. You do remember that?

6 A. Yeah.

7 Q. And did the DEA do that, submit --

8 A. Yes.

9 Q. Submit its changes?

10 A. Yes.

11 Q. And did the DEA support the legislation on
12 the version that actually passed?

13 A. We agreed to it. I wouldn't say supported
14 it.

15 Q. Okay, but you didn't object to it?

16 A. Yes, we did object to it.

17 Q. In the end?

18 A. In the end, I mean, we did not.

19 MR. SHKOLNIK: Objection to that conversation.
20 Object to form.

21 BY MR. NICHOLAS:

22 Q. Ultimately --

23 MR. SHKOLNIK: Objection to form.

24 BY MR. NICHOLAS:

25 Q. -- at the end of the process when the

1 legislation was passed, when it was about to be
2 passed, did the DEA assent to it?

3 MR. SHKOLNIK: Objection to form.

4 MS. BACCHUS: I have to object here. To the
5 extent that this requires the internal
6 deliberations, you cannot answer.

7 THE WITNESS: Okay.

8 BY MR. NICHOLAS:

9 Q. Did the DEA support the legislation and
10 the version of the legislation that actually
11 passed?

12 MR. SHKOLNIK: Objection.

13 MS. BACCHUS: Scope.

14 MR. SHKOLNIK: Form. Scope.

15 THE WITNESS: I'd say we agreed to it.

16 BY MR. NICHOLAS:

17 Q. Okay. Last set of questions, and then
18 someone else can ask you some questions.

19 Are you familiar with the annual
20 production quota?

21 MS. BACCHUS: Objection.

22 MR. SHKOLNIK: Objection. Outside the scope.

23 MS. BACCHUS: She cannot testify to quotas.
24 That was not part of her Touhy authorization.

25 THE WITNESS: Answer the question?

1 BY MR. NICHOLAS:

2 Q. You've been instructed not to answer.

3 MS. BACCHUS: I've instructed you not to answer
4 any questions regarding quotas.

5 MR. NICHOLAS: Can I ask a foundational
6 question to see if I can change your mind at all?
7 It's just a foundational question.

8 MS. BACCHUS: You can ask it. I don't know
9 that it's going to change my mind. If you look at
10 the Touhy authorization, there's nothing about
11 quotas.

12 BY MR. NICHOLAS:

13 Q. The question is during the course of your
14 employment with the DEA, did you ever work -- did
15 your work ever involve working with annual
16 production quotas?

17 MS. BACCHUS: I'm going to object to that and
18 instruct her not to answer.

19 MR. NICHOLAS: Okay. Rather than take issue
20 for the next half hour and bicker back and forth,
21 I'm just going to make a record of the fact that we
22 think she should be allowed to talk about this
23 because it's within the scope of the Touhy
24 permissive instructions because it has to do with
25 her prior -- it may, if she answers yes, have to do

1 with what she's done in her employment at DEA,
2 which I know I am allowed to inquire about.

3 So that's my basis for objecting to your
4 objection. If you're going to stick by your guns
5 and still instruct her not to answer, there's
6 nothing I can do.

7 MS. BACCHUS: Well, to the extent that you have
8 asked her what her general duties entailed, she can
9 tell you yes, if her general duties entailed it.
10 To the extent of getting into the details of quotas
11 and what she may have advised or had not advised,
12 what she had done with respect to quotas, we would
13 object that that is outside the scope of the Touhy
14 authorization. As you can review it, the
15 authorization was regarding suspicious orders.
16 There was no request for her to testify regarding
17 quotas, and so it has not been evaluated. So we
18 would stand on it.

19 MR. SHKOLNIK: I agree.

20 MR. NICHOLAS: You've been instructed not to
21 answer by your counsel. I'm going to respect the
22 instruction, obviously. So I've appreciated the
23 time you've given me, Ms. Ashley, to talk. And
24 since I'm pretty sure I haven't taken all that much
25 time, to the extent we have time left over at the

1 end, I'm going to reserve whatever is left over so
2 that I can ask some questions at the end, okay?
3 Thank you very much.

4 THE VIDEOGRAPHER: We're off the record at
5 2:19 p.m.

6 (Whereupon, a short break was
7 taken.)

8 THE VIDEOGRAPHER: We're back on the record at
9 2:26 p.m.

10 EXAMINATION

11 BY MS. ZOLNER:

12 Q. Hi, Ms. Ashley. My name is Erica Zolner,
13 and I represent one of the manufacturers in this
14 action. I'm going to ask you some questions now on
15 behalf of my client.

16 We talked this morning about Exhibit 3,
17 which is the Controlled Substances Act. If you
18 could pull that back out of your big pile of
19 documents, I'm going to ask you a few more
20 questions about that document. Just let me know
21 when you're there.

22 A. I'm there.

23 Q. Great. We're, again, going to talk
24 specifically about Section B of Section 1301.74 of
25 the Controlled Substances Act. You testified

1 earlier this morning about this statute based on
2 your over 35 years of experience at DEA. Do you
3 recall that?

4 A. Yes.

5 Q. And I seem to recall you saying that this
6 statute has not changed since 1971; is that right?

7 MS. BACCHUS: Objection. Mischaracterization.

8 THE WITNESS: I don't recall it changing.

9 BY MS. ZOLNER:

10 Q. Do you see the word suspicious in
11 Section B?

12 A. Yes.

13 Q. What is a suspicious order based on your
14 experience for a manufacturer?

15 A. In my experience, a suspicious order is
16 one that would sort of raise a flag with the
17 distributor or the person who's coordinating the
18 transaction that it's not the norm, the routine for
19 that particular customer.

20 Q. Is suspicious defined anywhere in the
21 Controlled Substances Act?

22 A. No.

23 Q. Is a suspicious order different for a
24 manufacturer versus a distributor?

25 A. No, not suspicious. If it's suspicious,

1 it's just suspicious.

2 Q. Okay. And to your knowledge, as you're
3 sitting here now, you're not aware of any
4 additional definition of suspicious in the
5 Controlled Substances Act; is that correct?

6 MR. SHKOLNIK: Objection to form.

7 THE WITNESS: In the Controlled Substances Act,
8 no.

9 BY MS. ZOLNER:

10 Q. Are you aware of a definition anywhere
11 other than in the Controlled Substances Act that is
12 relied on the DEA?

13 A. Yeah. There was policy guidance
14 published. I don't remember which year, but there
15 was policy guidance published in the Federal
16 Register.

17 Q. Other than the Federal Register, are you
18 aware of any other definitional phrasing --

19 A. No.

20 Q. -- for suspicious?

21 What about unusual in Section B, what is
22 meant by unusual size?

23 A. It would be different from the norm of the
24 size that that particular customer typically
25 orders.

1 Q. Different from the norm. So how much of a
2 deviation would make it unusual?

3 A. That would be determined by the
4 distributor or the manufacturer.

5 Q. So is there any threshold for determining
6 whether a deviation is unusual?

7 A. Not that the DEA sets, no.

8 Q. Based on your experience, would you agree
9 that there might be situations where an order is of
10 an unusual size, but the order is not suspicious?

11 A. Yes.

12 MR. SHKOLNIK: Objection. Outside the scope.

13 THE WITNESS: Is it possible? Yes.

14 BY MS. ZOLNER:

15 Q. Could you give me some examples of when
16 that might be the case?

17 MS. BACCHUS: Objection.

18 MR. SHKOLNIK: Objection.

19 MS. BACCHUS: If you know.

20 THE WITNESS: It might be the case, for
21 example, if there were some natural disaster where
22 that particular manufacturer/distributor lost their
23 supply -- not the manufacturer. I'm sorry. If the
24 retail pharmacy lost their supply of inventory and
25 they needed to reorder, but they needed to reorder

1 in bulk because they lost everything.

2 BY MS. ZOLNER:

3 Q. Can you think of other examples?

4 A. If somehow I have experience where there
5 is an incentive to purchase more, maybe end of year
6 sale or something to that effect.

7 Q. Any other examples?

8 A. Not that I can think of.

9 Q. Are there other examples that you just
10 can't think of?

11 A. Likely, yes.

12 MR. SHKOLNIK: Objection to form.

13 BY MS. ZOLNER:

14 Q. Likely, yes?

15 A. Yes.

16 Q. In Section B towards the end of Section B,
17 it says the registrant shall inform the field
18 division office of the administration in his area
19 of suspicious orders when discovered by the
20 registrant. Next sentence, suspicious orders
21 include orders of unusual size, orders deviating
22 substantially from a normal pattern and orders of
23 unusual frequency.

24 What do you interpret normal pattern to
25 mean in that sentence?

1 MR. SHKOLNIK: Objection. Are you asking her
2 for DEA's interpretation on that or this witness
3 personally?

4 MS. ZOLNER: There's a standing objection on
5 this issue.

6 MR. SHKOLNIK: I can make my objection to every
7 question.

8 MS. ZOLNER: I would ask that you please
9 refrain from speaking objections.

10 MR. SHKOLNIK: You can ask me all you want.
11 Are you asking for a personal, or are you -- is
12 this question personal or DEA? So the form of the
13 objection is very clear.

14 BY MS. ZOLNER:

15 Q. You can answer the question.

16 A. In my personal opinion, for a known
17 customer to place an order that's different from
18 what they normally place would be outside of the
19 normal pattern.

20 Q. What about deviating substantially in that
21 last sentence that I just read, what does that mean
22 to you based on your experience at DEA?

23 A. Based on my experience, if there is,
24 again, a known customer and if it's much larger
25 even than -- you know, much more larger than --

1 just enough to raise some sort of suspicion. So
2 it's just, I guess, the magnitude of the deviation.

3 Q. Is deviating substantially defined
4 anywhere that you're aware of?

5 A. Other than the guidance document that was
6 published, I don't know.

7 Q. Are you --

8 A. Not that I'm aware of.

9 Q. Are you referring again to that Federal
10 Register document that you just referred to
11 earlier?

12 A. Yes.

13 Q. Do you agree that there might be
14 situations where an order deviates substantially
15 from a normal pattern and is not suspicious?

16 MS. BACCHUS: Objection. Calls for
17 speculation. You can answer.

18 THE WITNESS: Yeah, that could happen.

19 BY MS. ZOLNER:

20 Q. To your knowledge, what is meant by
21 unusual frequency in the last sentence?

22 A. For a known customer to place an order
23 typically sooner than they normally would.

24 Q. In your experience, would you agree that
25 there might be situations when an order of unusual

1 frequency is not suspicious?

2 A. Yes, I would agree to that.

3 Q. Are there any other factors other than the
4 factors enumerated here that must be considered
5 when determining whether an order is suspicious?

6 MR. SHKOLNIK: Objection. Form. Outside the
7 scope unless you're asking for personal opinion.

8 MS. BACCHUS: Objection.

9 THE WITNESS: In my personal opinion, yes.

10 BY MS. ZOLNER:

11 Q. What are those factors?

12 A. I wouldn't be able to name them all. It
13 could be lots of things. It could be the location
14 of the customer. It could be the population that
15 the customer supplies. It could be a lot of
16 different things. I wouldn't be able to name them
17 all.

18 Q. Based on your experience, why haven't
19 those factors that you just described been added to
20 the Controlled Substances Act?

21 MR. SHKOLNIK: Objection. Outside the scope.
22 Policy.

23 MS. BACCHUS: Objection. She can't speak to
24 what DEA would or would not do.

25

1 BY MS. ZOLNER:

2 Q. To your knowledge, are you aware of any
3 other place where DEA has defined any of the terms
4 other than the Federal Register for terms that are
5 used in Section B?

6 MR. SHKOLNIK: Objection.

7 MS. BACCHUS: Objection. Asked and answered.

8 MR. SHKOLNIK: Asked and answered.

9 THE WITNESS: Other than the Controlled
10 Substances Act and the Code of Federal Regulations
11 and the guidance document?

12 BY MS. ZOLNER:

13 Q. Yes.

14 A. In policy letters.

15 Q. Other than policy letters, any other
16 sources?

17 MR. SHKOLNIK: Objection. Form.

18 THE WITNESS: I don't know.

19 BY MS. ZOLNER:

20 Q. You're familiar with the term controlled
21 substances, right? We've been talking a lot about
22 the Controlled Substances Act this morning. Based
23 on your knowledge, are prescription opioids
24 controlled substances?

25 A. Prescription opioids, yes, they are.

1 Q. Are you familiar with the phrase closed
2 system of distribution?

3 A. Yes.

4 Q. What does that mean?

5 A. It means from development of the drug,
6 manufacturing of the drug, that DEA maintains
7 control in that system from registrant to
8 registrant until it exits to the ultimate user.

9 Q. Did you say DEA maintains?

10 A. Maintains authority over the transactions
11 of the controlled substance until it exits.

12 Q. Until it exits, what do you mean by that?

13 A. When it's given to the ultimate user,
14 prescribed to the ultimate user.

15 Q. So it's your testimony that DEA would
16 maintain control over the drug in a controlled
17 system of distribution?

18 MS. BACCHUS: Objection. Mischaracterization.

19 THE WITNESS: No. No.

20 BY MS. ZOLNER:

21 Q. I misunderstood your testimony.

22 A. I'm thinking physical control as in having
23 possession of it, no. I mean, that they would have
24 regulatory authority over the transactions with its
25 regulatory control. It's the paperwork, the

1 invoices and the documents that would show where
2 the controlled substances are going.

3 Q. Are there different categories of
4 registrants under DEA regulations?

5 A. Yes.

6 Q. Can you give me some examples?

7 A. I'm sorry. Let me clarify. Do you mean
8 business activity when you say category?

9 Q. I meant in terms of registrants, you have
10 pharmacies, right?

11 A. Uh-huh. That's a business activity.

12 Q. I'm sorry?

13 A. I'm sorry. That would be the business
14 activity, pharmacies, manufacturers, the type of
15 business that they --

16 Q. Exactly. The kind of business that a
17 particular registrant engages in, there can be
18 different categories of registrants engaged in
19 different categories of business, correct?

20 A. Correct.

21 Q. Manufacturers --

22 A. Yes.

23 Q. -- manufacture substances. Distributors
24 distribute them. Is everyone involved in the
25 production or sale of controlled substances playing

1 a different role in the closed system in your view?

2 MR. SHKOLNIK: Objection to form and outside
3 the scope unless it's her personal opinion.

4 THE WITNESS: I don't think I'm clear on the
5 question. The role would be to operate in
6 compliance with the Controlled Substances Act, so
7 they may all have the same role.

8 BY MS. ZOLNER:

9 Q. But the different categories of
10 registrants that we just discussed, they have
11 different business activities, right? We just
12 described that?

13 A. Correct.

14 Q. So with respect to those different
15 business activities, those different business
16 activities require different responsibilities
17 depending on what kind of a registrant you are,
18 right?

19 A. Yes.

20 Q. Just so you know with the court reporter,
21 nodes are very difficult to record.

22 A. Oh.

23 Q. That's the only reason why I paused.

24 Do manufacturers have the same visibility,
25 based on your knowledge, into sales to pharmacies

1 as distributors?

2 A. Sometimes, yes.

3 Q. Do they always have the same visibility
4 into sales to pharmacies as distributors?

5 MR. SHKOLNIK: Objection to form.

6 THE WITNESS: I don't know.

7 BY MS. ZOLNER:

8 Q. You said sometimes, yes. Could you
9 explain and clarify what you meant by that?

10 A. When I say sometimes, yes, it's only if
11 the distributor provides it, and I know that
12 sometimes they do.

13 Q. Okay. So if I'm understanding your
14 testimony, if the distributor shares information
15 about a pharmacy customer with a manufacturer, then
16 the manufacturer has transparency into sales to
17 that pharmacy?

18 A. Yes.

19 Q. Do distributors have the same visibility
20 into sales to patients as pharmacies?

21 MR. SHKOLNIK: Objection to form.

22 MS. BACCHUS: Based on your knowledge.

23 THE WITNESS: Again, sometimes.

24 BY MS. ZOLNER:

25 Q. Sometimes. Would that be similar to

1 the --

2 A. Yeah.

3 Q. -- way we just described when a
4 manufacturer would have visibility into a pharmacy?
5 That would only occur, as we just discussed, if the
6 distributor provided that information to the
7 manufacturer, right?

8 MR. SHKOLNIK: Objection. Form.

9 MS. BACCHUS: Objection.

10 MR. SHKOLNIK: Speculation.

11 THE WITNESS: If the retail pharmacy provides
12 the information to the distributor, they would have
13 it.

14 BY MS. ZOLNER:

15 Q. Right. So to take the next example
16 whether distributors would have the same visibility
17 into sales to patients as pharmacies, that
18 visibility would only occur if the pharmacies
19 provided that information, right?

20 MR. SHKOLNIK: Objection to form.

21 THE WITNESS: That's the one way I know of,
22 yes.

23 BY MS. ZOLNER:

24 Q. Is each participant in the closed system
25 of distribution, to your knowledge, responsible for

1 knowing their own customers?

2 A. Yes.

3 Q. Does each participant in the closed system
4 of distribution have corresponding responsibility
5 for their direct sales of controlled substances?

6 A. Yes.

7 Q. Have you ever heard of the phrase know
8 your customer's customer?

9 A. Yes.

10 Q. What does that mean?

11 A. It means if you have a customer that
12 you're supplying to that you want to make sure that
13 they are making sales to legitimate customers, that
14 they are a legitimate business and they have
15 customers supporting the business that they want
16 from you.

17 Q. It means -- I'm just looking at your
18 testimony. I want to make sure I understand it.
19 It means if you have a customer that you're
20 supplying to, you want to make sure that they're
21 making sales to legitimate customers, but does that
22 require you to know all of the details about -- for
23 instance, if you are supplying prescription drugs
24 to a distributor, does that require you to know all
25 of the details of the distributor's customer base?

1 MR. SHKOLNIK: Objection. You're asking for
2 DEA's position and the law here. Objection to
3 form, first of all. Objection to asking for a
4 position of the DEA.

5 MS. ZOLNER: I would again respectfully ask
6 that you refrain from speaking objections. I'll
7 say it every time so the record is clear. Form
8 objections and objection to --

9 MR. SHKOLNIK: I'm allowed at least 10 words.
10 That's the rule. I've done enough of these.

11 MS. ZOLNER: If you're comfortable taking that
12 position. I would again just request no speaking
13 objections respectfully.

14 MS. BACCHUS: Can I ask that you slow down a
15 little bit.

16 MS. ZOLNER: Sure. You know, it's funny. I'm
17 making a big effort to slow down, so I'll make even
18 more of an effort to slow it down.

19 BY MS. ZOLNER:

20 Q. Okay. Going back to know your customer's
21 customer, to your knowledge, is there any language
22 in the Controlled Substances Act that states that a
23 manufacturer is required to know its customer's
24 customer?

25 A. In the Controlled Substances Act, no.

1 Q. Is that phrase anywhere in the CSA to your
2 knowledge?

3 A. To my knowledge, no.

4 Q. To your knowledge, is there any language
5 in the Code of Federal Regulations that states that
6 a manufacturer is required to know its customer's
7 customer?

8 MR. SHKOLNIK: Objection. Form.

9 THE WITNESS: I have to say I'm not sure to
10 that one.

11 BY MS. ZOLNER:

12 Q. You just don't know one way or another?

13 A. Correct.

14 MR. SHKOLNIK: Objection to form.

15 BY MS. ZOLNER:

16 Q. As you sit here today, are you aware of
17 any statute that requires a manufacturer to know
18 its customer's customer?

19 A. No, I am not aware of a statute that says
20 that.

21 Q. What about a regulation?

22 A. No, I'm not aware of a regulation that
23 says that.

24 Q. What about a formal notice that's been
25 promulgated by DEA?

1 MR. SHKOLNIK: Objection to form.

2 THE WITNESS: I'd have to say I don't know.

3 BY MS. ZOLNER:

4 Q. Are you aware of any correspondence from
5 DEA to manufacturers explaining that manufacturers
6 are responsible for knowing their customer's
7 customer?

8 A. I can't recall any.

9 Q. So to your knowledge, where is this phrase
10 know your customer's customer coming from?

11 A. My recollection is it comes from Federal
12 Register notices after final orders. I remember
13 reading them in final orders.

14 Q. You recall the language know your
15 customer's customer being formally written in final
16 orders? Is that your testimony?

17 A. I remember those terms being used.

18 MR. SHKOLNIK: Objection to form.

19 THE WITNESS: Exactly how they were used, I
20 don't remember, but I do remember those terms being
21 used.

22 BY MS. ZOLNER:

23 Q. In your opinion, how is a manufacturer
24 expected to know its customer's customer?

25 MS. BACCHUS: Objection. You can answer if you

1 have an opinion.

2 THE WITNESS: My opinion is in exercising due
3 diligence -- you're speaking from a manufacturer
4 knowing its customer's customer? That was the
5 question?

6 BY MS. ZOLNER:

7 Q. Correct.

8 A. If they're supplying to a customer, which
9 is the distributor, in my opinion, in exercising
10 due diligence, you want to know that the
11 distributor is distributing to customers that are
12 real and that can support the amount of controlled
13 substances that the distributor has ordered.

14 Q. Based on your experience, did DEA provide
15 guidance as to how a manufacturer was supposed to
16 engage in due diligence on a distributor's
17 customers?

18 MR. SHKOLNIK: I'm sorry. Objection to form.

19 THE WITNESS: Yes. There were policy and final
20 order documents that laid those things out.

21 BY MS. ZOLNER:

22 Q. Which policy and final --

23 A. I don't recall.

24 THE COURT REPORTER: I'm sorry. One more time,
25 please.

1 BY MS. ZOLNER:

2 Q. Again, it gets tricky because we write
3 everything that we're both saying down.

4 Which policy and final order documents are
5 you referring to?

6 A. I just recall reading many over the years.
7 I couldn't specifically pull out a name.

8 Q. Did you personally write any policy or
9 final order documents where you described how a
10 manufacturer should attempt to know its customer's
11 customer?

12 A. No.

13 Q. As you sit here today, are you aware of
14 any specific final order documents where the
15 process for how a manufacturer was expected to know
16 its customer's customer was described?

17 MR. SHKOLNIK: Objection to form.

18 THE WITNESS: I don't recall the name of one.

19 BY MS. ZOLNER:

20 Q. Are you aware of any descriptive document
21 that has ever been promulgated by DEA that
22 describes how due diligence should work around
23 knowing a customer's customer?

24 A. I'm going to say I don't recall.

25 Q. Do you know if DEA ever informed

1 manufacturers formally that they were required to
2 know their customer's customer?

3 A. Did they ever require it? Not to my
4 knowledge, no.

5 Q. Earlier today you saw two different --
6 actually, I think you only saw the 2007 dear
7 registrant letter that was signed by
8 Mr. Rannazzisi. Do you remember that letter?

9 A. Yes.

10 Q. I don't think we need to pull that out,
11 but maybe we should. I'll get you a number so you
12 can find it in your pile more easily.

13 MR. SHKOLNIK: 5.

14 MS. ZOLNER: Is it 5? Thank you.

15 BY MS. ZOLNER:

16 Q. Do you know if this letter, and take a
17 minute to look over the letter, does it mention an
18 obligation for manufacturers to know your
19 customer's customer?

20 A. No, it doesn't state that in this letter.

21 Q. I think you testified earlier this morning
22 that there has been no additional dear registrant
23 letter promulgated by DEA since the letter you're
24 looking at, Exhibit 5; is that right?

25 MR. SHKOLNIK: Objection. Form. Misstates

1 prior testimony.

2 THE WITNESS: You're speaking specific to
3 suspicious orders as when a dear registrant letter
4 had gone out regarding suspicious orders?

5 BY MS. ZOLNER:

6 Q. Correct.

7 A. No, not to my knowledge. No.

8 Q. Are you aware of any manufacturer
9 initiative where DEA explained the concept of know
10 your customer's customer to manufacturers?

11 A. A manufacturer's initiative, no, I'm not
12 aware of that.

13 Q. Let's put Exhibit 5 aside. I'm switching
14 to a new topic.

15 Are you familiar with the term chargeback
16 data?

17 A. I'm familiar with it, yes.

18 Q. What does that mean?

19 A. To me, it means it's the data that is
20 shared back to the manufacturer from the
21 distributor after making a purchase. The
22 distributors receive some sort of incentive to
23 provide the information data of who their customers
24 are back to the manufacturer.

25 Q. Okay. I want to take apart what you just

1 said and make sure I understand it.

2 Is data always shared back between
3 distributors and manufacturers --

4 MR. SHKOLNIK: Objection to form.

5 BY MS. ZOLNER:

6 Q. -- related to a distributor's customers?

7 MS. BACCHUS: Objection to form.

8 MR. SHKOLNIK: Objection.

9 MS. BACCHUS: If you know.

10 THE WITNESS: I don't know.

11 BY MS. ZOLNER:

12 Q. You don't know if that data is always
13 shared?

14 A. I don't know if it always is.

15 Q. You said -- you used the word incentive,
16 and you said distributors receive some sort of
17 incentive to provide the information or data back
18 to the manufacturer.

19 What did you mean by that term incentive?

20 A. So in my knowledge, it was some -- it was
21 incentives, maybe a discount. I guess I just used
22 the word discount. That's what my knowledge is.

23 Q. Incentive, in your experience, equates to
24 discount?

25 A. Yeah.

1 Q. To the best of your understanding, does
2 chargeback data play any role in suspicious order
3 monitoring?

4 A. I guess I'm not clear. On behalf of the
5 DEA, you mean is that something that we would use
6 or the distributor? Would it play a role in what
7 they do?

8 Q. Based on your experience --

9 A. In my experience -- I'm sorry.

10 Q. Sure. Let me try again.

11 Based on your experience with DEA, did DEA
12 view chargeback data as playing any kind of a role
13 in suspicious order monitoring?

14 MS. BACCHUS: Objection to form.

15 MR. SHKOLNIK: Objection to form.

16 MS. BACCHUS: She can't answer about what DEA
17 did. She can tell you what her knowledge is.

18 THE WITNESS: In my experience, chargeback data
19 was used in suspicious order monitoring information
20 by registrant.

21 BY MS. ZOLNER:

22 Q. How?

23 A. In my experience, they use it in order to
24 determine where they sell controlled substances.

25 Q. In your view and in your experience, is

1 there any limitation to what kind of information
2 chargeback data can provide?

3 A. No, I don't know that.

4 Q. You don't know?

5 A. No.

6 Q. In your experience, is chargeback data
7 typically submitted to a manufacturer by a
8 distributor?

9 MR. SHKOLNIK: Objection. Objection to form.

10 MS. BACCHUS: If you know, you can answer.

11 THE WITNESS: In my experience, it was provided
12 back to the manufacturer from the distributor.

13 BY MS. ZOLNER:

14 Q. Do you know if that data was provided to
15 the manufacturer after the product shipped?

16 A. To my knowledge, it was after the product
17 shipped.

18 Q. Do you know if manufacturers receive
19 chargeback data from all distributors?

20 A. I do not know.

21 Q. You don't know one way or another?

22 A. If all manufacturers receive chargeback
23 data from all distributors, no, I do not know that.

24 Q. Do you know if chargeback data is only
25 shared if manufacturers and distributors have a

1 chargeback agreement in place?

2 MR. SHKOLNIK: Objection to form.

3 THE WITNESS: I don't know that.

4 BY MS. ZOLNER:

5 Q. You don't know one way or another?

6 A. I do not.

7 Q. Do you know anything about chargeback
8 agreements?

9 MR. SHKOLNIK: Objection.

10 THE WITNESS: No.

11 BY MS. ZOLNER:

12 Q. No?

13 Do you know if manufacturers would only
14 receive chargeback data from distributors if
15 manufacturers have agreed to pay a chargeback?

16 MR. SHKOLNIK: Objection to form.

17 THE WITNESS: I don't know that.

18 BY MS. ZOLNER:

19 Q. Did you say I don't know that?

20 A. I don't know that.

21 Q. And I assume that you also don't know if
22 manufacturers always have chargeback agreements in
23 place for every product; is that right?

24 MS. FRANKLIN: Objection. Form.

25 THE WITNESS: I don't know that.

1 BY MS. ZOLNER:

2 Q. I'm sorry. Your voice dropped.

3 A. I'm sorry. I don't know that.

4 Q. Do you know if chargeback data submitted
5 by a distributor would only contain the
6 distributor's downstream sales?

7 A. No, I don't know that.

8 Q. You don't know that one way or the other?

9 A. I don't know.

10 Q. So you don't know if the distributor would
11 be providing information on sales by other
12 distributors or not?

13 MS. BACCHUS: Objection. Asked and answered.

14 MR. SHKOLNIK: Objection to form. Speculative.

15 THE WITNESS: I don't know that. I don't know
16 that.

17 BY MS. ZOLNER:

18 Q. Do you know if chargeback data that would
19 be submitted by a distributor would only contain
20 sales of the specific manufacturer's product?

21 MR. SHKOLNIK: Objection to form. Speculative.

22 THE WITNESS: I don't know.

23 BY MS. ZOLNER:

24 Q. You don't know that.

25 Do you know if manufacturers, assuming

1 they get chargeback data, do you know if they can
2 only get chargeback data for products with their
3 own NDC codes?

4 A. I don't know that.

5 Q. Do you know -- do you know if chargeback
6 data only contains information on a number of units
7 for which a distributor is seeking a chargeback?

8 A. No, I don't know that.

9 MR. SHKOLNIK: Objection. Form.

10 BY MS. ZOLNER:

11 Q. No, I don't know that?

12 A. No, I don't know that.

13 Q. I'm sorry. I'm not trying to repeat what
14 you said. I'm just making sure I'm hearing you
15 accurately.

16 Are you aware of any instance, based on
17 your 35 years with DEA, where DEA informed
18 registrants that they should monitor chargeback
19 data?

20 MR. SHKOLNIK: Objection to the extent you're
21 asking outside of her personal knowledge.

22 THE WITNESS: Can I ask you a question? Can we
23 break? I need to ask you a question.

24 MS. BACCHUS: About privilege?

25 THE WITNESS: Yeah.

1 MS. BACCHUS: Do you mind if we go off the
2 record?

3 MS. ZOLNER: No. Absolutely.

4 THE VIDEOGRAPHER: We are off the record at
5 2:57 p.m.

6 (Whereupon, a short break was
7 taken.)

8 THE VIDEOGRAPHER: We're back on the record at
9 3:00 p.m.

10 MS. BACCHUS: To the extent that you have
11 knowledge outside of privileged information that
12 was involved in your communications with any of the
13 third parties, you may answer, but you may not
14 disclose any privileged communications.

15 THE WITNESS: Okay.

16 BY MS. ZOLNER:

17 Q. I think I can withdraw the question and
18 maybe try to give you a question that's easier to
19 answer.

20 Are you aware, as you sit here today, of
21 an instance in which DEA informed all registrants
22 that they should monitor chargeback data?

23 MR. SHKOLNIK: Objection to form.

24 THE WITNESS: I am not.
25

1 BY MS. ZOLNER:

2 Q. Are you aware of any instance in which DEA
3 informed manufacturers that there was a legal
4 obligation to monitor chargeback data?

5 A. I wouldn't want to say DEA. I'm aware
6 that I have not.

7 Q. Understanding your caveat there, are you
8 aware of anyone else at DEA ever communicating to
9 manufacturers that there was a legal obligation to
10 monitor chargeback data?

11 MR. SHKOLNIK: Objection.

12 THE WITNESS: I am not.

13 BY MS. ZOLNER:

14 Q. Thank you.

15 I'm going to show you a new document now.

16 (Whereupon, ASHLEY Deposition
17 Exhibit No. 20 was marked for
18 identification.)

19 BY MS. ZOLNER:

20 Q. Ms. Ashley, I'm going to ask you about the
21 page that has a Bates number in the lower
22 right-hand corner of 5926 as well as the document
23 that starts on this page with the Bates number
24 5928.

25 A. Okay.

1 Q. Have you seen this document before?

2 A. I don't recall.

3 Q. What are OD policy letters?

4 A. So if it's from the Office of Diversion
5 Control, typically if they have a response to a
6 registrant that they feel affects the national
7 diversion control program, they'll send a copy of
8 the letter out to all of diversion.

9 Q. Okay. And when you say that they'll send
10 a copy of the letter out to all of diversion, do
11 you mean that a copy of the letter goes to all of
12 the internal diversion employees within DEA?

13 A. Just the diversion control staff.

14 Q. Understood. And to your knowledge, what
15 is the purpose of submitting that policy letter to
16 the diversion control staff?

17 A. It's to help all divisions to be
18 consistent when we engage with registrants.

19 Q. Does OD stand for Office of Diversion?

20 A. Yes.

21 Q. And it says here that this letter was sent
22 to all diversion program managers, group
23 supervisors and senior diversion investigators.
24 Are those the diversion control staff?

25 A. Yes.

1 Q. Who sent the Office of Diversion policy
2 letters?

3 A. Here it was Deirdre McDowell. She was the
4 program analyst in the Office of Diversion in
5 headquarters.

6 Q. Did various people send out these letters
7 whenever these communications occurred?

8 A. Various people in the policy section.

9 Q. Was Deirdre McDonnell in DEA headquarters?

10 A. Yes.

11 Q. She was in the Office of Diversion
12 Control, the liaison and policy section at DEA
13 headquarters?

14 A. Yes.

15 Q. Do you know how often these letters were
16 issued?

17 A. I don't. I don't.

18 Q. Did you read these letters when they hit
19 your inbox?

20 A. Yes.

21 Q. And I see your name with a name -- a last
22 name that starts with A. You're at the top of the
23 food chain on the page labeled 5925. Do you see
24 your name there?

25 A. Yes.

1 Q. So do you have any reason to believe you
2 didn't receive this communication?

3 A. I have no reason to believe I did not.

4 Q. Were these letters shared with diversion
5 investigators?

6 A. Yes.

7 Q. In this letter, it says to share this
8 information with the diversion investigators in
9 your group, right?

10 A. Yes.

11 Q. Was it your practice to do so?

12 A. Yes.

13 Q. Did you ever assist in drafting letters
14 like the letter that's contained in Exhibit 5 --
15 Exhibit 20?

16 A. Yes.

17 Q. Could you look at the page that begins
18 with the Bates number 5931 in the lower right-hand
19 corner? Was this a letter -- do you understand to
20 this to be a letter from Allscript Pharmacy, Inc.?

21 A. Yes, I do.

22 Q. Did you understand Allscript Pharmacy,
23 Inc. to be drafting this letter requesting for
24 verification of controlled substances -- substance
25 dispensing practices at its pharmacy?

1 A. Let me read it.

2 Q. I'm reading the first line after to whom
3 it may concern.

4 A. Yes.

5 Q. Did you understand this letter to contain
6 information about the doctors and clinics that
7 Allscript serves?

8 A. Do I understand the letter -- I'm sorry.
9 Could you repeat the question?

10 Q. Sure. Did you understand this letter to
11 contain information about the doctors and the
12 clinics that Allscript Pharmacy works with?

13 MR. SHKOLNIK: Objection to form.

14 MS. BACCHUS: Can we have a time frame that
15 you're talking about?

16 BY MS. ZOLNER:

17 Q. At the time this letter was sent in 2008.

18 A. As I read this letter here today, I
19 understand it to speak about these physicians, yes.

20 Q. Do you see where the author of this
21 letter, Lucas Stahl, says below is a breakdown of
22 our average daily use by units for a few
23 medications? It's right before the --

24 A. I see it, yes.

25 Q. And then after four different medications

1 are listed, it says I hope that this information is
2 helpful in our appeal for an increase in our
3 ordering limits for some of these medications. Did
4 I read that correctly?

5 A. Yes.

6 Q. Did you understand Allscript to be asking
7 for an increase to its ordering limits?

8 MR. SHKOLNIK: Objection.

9 THE WITNESS: In this letter, that's my
10 understanding, yes.

11 BY MS. ZOLNER:

12 Q. Allscript then forwarded this letter to
13 the DEA on March the 21st, 2008, right?

14 MS. BACCHUS: Objection. Form. If you know.

15 MR. SHKOLNIK: Note my objection. I thought we
16 were not supposed to go into individual actions by
17 DEA, which appears to be what we're doing here.

18 BY MS. ZOLNER:

19 Q. I'm on Page 5930.

20 A. Okay. Okay. Do you have a question?

21 Q. Sure. Do you see where it says Harvard
22 Drug Group, in an attempt to raise our limits on
23 certain controlled substances, requested this
24 letter be sent to their office and the local Drug
25 Enforcement Agency. Do you see that?

1 A. Yes.

2 Q. Based on your experience, what is your
3 understanding as to why a pharmacy would send a
4 letter like this to DEA requesting an increase in
5 daily ordering limits?

6 MS. BACCHUS: Objection. Calls for
7 speculation. If you know, you can answer based on
8 your personal knowledge.

9 THE WITNESS: From my personal knowledge, no, I
10 do not know why they would do that.

11 BY MS. ZOLNER:

12 Q. Do you think the pharmacy was looking for
13 guidance on how to comply with the Controlled
14 Substances Act?

15 MS. BACCHUS: Objection. Calls for
16 speculation.

17 MR. SHKOLNIK: I'm sorry. Objection to form.

18 THE WITNESS: Do I think they were looking for
19 guidance?

20 MR. SHKOLNIK: Objection. Speculation. I'm
21 sorry.

22 THE WITNESS: Reading this here, no, I wouldn't
23 say they were looking for guidance. They were
24 looking for an increase.

25

1 BY MS. ZOLNER:

2 Q. Okay. I know we talked this morning about
3 the fact that registrants were often asking for
4 additional guidance from DEA on how to comply with
5 the Controlled Substances Act. Do you recall
6 testifying on those issues?

7 A. Yes.

8 Q. And I think you testified that again and
9 again registrants were asking questions and seeking
10 clarifications from DEA, right?

11 A. In my personal interactions, yes. Yes.

12 Q. So have you seen letters like the letter
13 we're looking at now in Exhibit 20 during your
14 tenure at DEA where pharmacies were asking for
15 increases in their limits?

16 MR. SHKOLNIK: Objection to form.

17 THE WITNESS: No. I mean, no, I don't recall
18 seeing a letter of this sort. No.

19 BY MS. ZOLNER:

20 Q. On May the 14th, 2008, the DOJ responded
21 to the Allscript letter, and that response starts
22 at 5928 on Exhibit 20. Let me know when you're
23 there.

24 A. I am.

25 Q. I'm just going to ask you about the first

1 paragraph. Do you see where it says the Harvard
2 Drug Group requested that you submit a letter to
3 DEA to substantiate your request to them to raise
4 your purchase limits on certain controlled
5 substances? Please be advised that DEA does not
6 set limits on what a distributor may sell to a
7 pharmacy. Consequently, requests for sales
8 increases of controlled substances are solely the
9 consideration of the distributor.

10 Did I read that correctly?

11 A. Yes.

12 Q. Do you know if the DEA ever informed the
13 Harvard Drug Group whether Allscript's explanation
14 for its controlled substance demand was accurate?

15 MS. BACCHUS: Objection. Form. You can answer
16 if you know.

17 THE WITNESS: I do not know.

18 BY MS. ZOLNER:

19 Q. If you look on the next page, there's some
20 bolded language on 5929, and the first bolded
21 sentence says the decision to ship controlled
22 substances to a particular customer rests with the
23 supplier. Do you see that?

24 A. Yes.

25 Q. Is it your understanding that DEA would

1 not provide input about whether increasing order
2 limits would be acceptable?

3 A. In my experience, no, we would not.

4 Q. Like you testified this morning, those
5 decisions are exclusively left up to the supplier,
6 right?

7 A. Yes.

8 MS. BACCHUS: Objection. Asked and answered.

9 MR. SHKOLNIK: Objection to form.

10 BY MS. ZOLNER:

11 Q. Would you say that was DEA's policy, in
12 your experience, to leave those sorts of decisions
13 on controlled substances up to a particular
14 customer?

15 MR. SHKOLNIK: Objection to form.

16 MS. BACCHUS: Objection to form.

17 BY MS. ZOLNER:

18 Q. To a particular supplier.

19 MS. BACCHUS: Same objection.

20 MR. SHKOLNIK: Same.

21 THE WITNESS: Was it policy? Yes, it is.

22 BY MS. ZOLNER:

23 Q. Okay. Let's put that aside.
24
25

1 (Whereupon, ASHLEY Deposition
2 Exhibit No. 21 was marked for
3 identification.)

4 BY MS. ZOLNER:

5 Q. This is Exhibit 21. Ms. Ashley, is this
6 another OD policy letter?

7 A. Yes.

8 Q. If you could turn to the page with 5923 in
9 the corner, this is a letter that was written to
10 the Martinsville -- this is a letter that was
11 written from the Martinsville Family Pharmacy, Inc.
12 to Donetta Spears at DEA, and you received this
13 letter, correct?

14 A. Did I receive it? You mean in -- if I'm
15 in the top there, yeah, I would have.

16 Q. Yes. So if we turn back to --

17 A. Yes, I did.

18 Q. Great. So just for the record, if we turn
19 back to the first page of Exhibit 21, again, you're
20 at the very top of the recipient list, Ashley,
21 comma, Demetra, right? So you received this letter
22 from the Martinsville Family Pharmacy?

23 MS. BACCHUS: Objection. Asked and answered.
24 You can answer.

25 THE WITNESS: I don't recall specifically, but

1 yes, I have no reason to believe I didn't.

2 BY MS. ZOLNER:

3 Q. If you could turn your attention to the
4 second paragraph that starts on Tuesday,
5 December 11th, it says on Tuesday, December 11th, I
6 was alerted by a representative of Cardinal Health,
7 our wholesaler that we would not be able to
8 purchase scheduled drugs, those substances which
9 are regulated by the DEA, the Drug Enforcement
10 Agency. Though an official reason was not given,
11 it was noted that the pharmacy was on a list of
12 pharmacies which were being watched by the DEA, and
13 due to a close review of Cardinal Health's
14 practices, these actions were required. Officials
15 at Cardinal felt they were being forced to limit
16 the sales of controlled substances, comma,
17 particularly to the pharmacies on this list.

18 Did I read that right?

19 A. Yes.

20 Q. Do you know what list is being referred to
21 here?

22 A. No.

23 Q. If you look on Page 5924, I'm looking
24 specifically at the very last paragraph. It says I
25 now ask for your assistance. If there is anything

1 that I need to do or can do to resolve whatever
2 grievance that the DEA may have with my business,
3 please let me know.

4 Did I read that correctly?

5 A. Yes.

6 Q. And then the very last sentence before
7 Robert Pratt, the pharmacist and owner signs off,
8 is I simply need to know what I should be doing
9 differently.

10 Did I read that correctly?

11 A. Yes.

12 Q. Was this type of request where a
13 registrant was asking for guidance from DEA about
14 how to comply with rules, were these routine
15 requests in your view?

16 MR. SHKOLNIK: Objection. Form.

17 MS. BACCHUS: Objection. Vague.

18 THE WITNESS: This specific type I'd have to
19 say I don't know. Registrants always ask
20 questions.

21 BY MS. ZOLNER:

22 Q. Registrants always ask questions?

23 A. Sure.

24 Q. And a question like this, this wasn't
25 unusual in your view, right?

1 MS. BACCHUS: Objection. Form.

2 THE WITNESS: No, it wasn't unusual in my view.

3 BY MS. ZOLNER:

4 Q. How often would you estimate that these
5 types of requests for guidance came in by
6 registrants?

7 MS. BACCHUS: Objection. Asked and answered.

8 MR. SHKOLNIK: Objection.

9 THE WITNESS: It would be hard for me to guess.
10 I don't know how often.

11 BY MS. ZOLNER:

12 Q. More than three times a month?

13 MR. SHKOLNIK: Objection. Speculation.

14 THE WITNESS: Yes.

15 BY MS. ZOLNER:

16 Q. More than 10 times a month?

17 A. I don't know.

18 Q. They were frequent?

19 A. Yes.

20 Q. As you sit here today, can you provide any
21 kind of an estimate on frequency?

22 MS. BACCHUS: Objection. Asked and answered.
23 You can answer.

24 THE WITNESS: I would say more than three, less
25 than 10. That would be my estimate.

1 BY MS. ZOLNER:

2 Q. And I know we talked earlier this morning
3 about the shift in leadership in early 2015. You
4 talked earlier this morning about the fact that you
5 and Mr. Milione set out to start setting up
6 meetings with registrants, answering
7 more questions.

8 As you sit here today, do you think that
9 the questions coming in from registrants were more
10 frequent prior to when you started setting up those
11 meetings and sitting down with registrants to
12 answer questions about how to comply?

13 A. I wouldn't be able to judge that. I don't
14 know.

15 Q. If you could now look at Exhibit 21, if
16 you could turn to the response that came in from
17 DEA, it starts on Page 5921. You can take a minute
18 to look over this letter, and then I'll ask you a
19 few questions about it.

20 A. Okay.

21 Q. You've had a chance to review the letter?

22 A. Yes, the response.

23 Q. Does the letter inform the Martinsville
24 Family Pharmacy that they are, indeed, on a list of
25 pharmacies which are being watched by the DEA?

1 A. No, it does not.

2 Q. Does the letter tell the Martinsville
3 Family Pharmacy they are not on a list of
4 pharmacies which were being watched by the DEA?

5 MS. BACCHUS: Objection. If you know.

6 THE WITNESS: No.

7 BY MS. ZOLNER:

8 Q. No, it doesn't say anything about that?

9 MS. BACCHUS: Objection. Asked and answered.

10 THE WITNESS: No.

11 BY MS. ZOLNER:

12 Q. Does the letter say anything about a list
13 of pharmacies that are being watched?

14 MS. ZOLNER: Can someone on the phone please go
15 on mute? We are getting a lot of interference.

16 BY MS. ZOLNER:

17 Q. I'll go back to my question. Does the
18 letter say anything about a list of pharmacies
19 which were being watched by the DEA?

20 MR. SHKOLNIK: Objection to form.

21 THE WITNESS: It does not.

22 BY MS. ZOLNER:

23 Q. It does not?

24 MR. SHKOLNIK: Form.

25 THE WITNESS: No.

1 BY MS. ZOLNER:

2 Q. Does the letter make any suggestions about
3 what the Martinsville Family Pharmacy can do
4 differently to avoid being watched by the DEA?

5 MS. BACCHUS: Objection.

6 MR. SHKOLNIK: Object to form.

7 THE WITNESS: Could you repeat that?

8 BY MS. ZOLNER:

9 Q. Sure. Does the letter make any
10 suggestions about things the Martinsville Family
11 Pharmacy can do differently to avoid being watched
12 by DEA?

13 MR. SHKOLNIK: Objection to form.

14 THE WITNESS: In my opinion, yes.

15 BY MS. ZOLNER:

16 Q. What?

17 A. Establishing a suspicious order monitoring
18 program.

19 Q. Where do you see that?

20 A. On Page 2.

21 Q. Could you tell me exactly where you're
22 looking on Page 2 and what you're referring to as
23 Page 2? Is it Page 5922?

24 A. I'm sorry. 5922.

25 Q. Thank you.

1 A. In furtherance of 21 USC 823.

2 Q. Okay. So just for the record, you're
3 referring to the first full paragraph on 5922,
4 which starts in furtherance of 21 USC Section
5 823(a)(1), right?

6 A. Yeah.

7 Q. Okay. What in that paragraph do you
8 contend provides guidance to the Martinsville
9 Family Pharmacy on what they need to do
10 differently?

11 A. Let me take that back. You said what they
12 would need to do differently. I understood the
13 question as what guidance did it provide to them
14 that would help them ensure compliance with the
15 Controlled Substances Act. I read too much into
16 the question, so I'll take back what I said.

17 Q. Okay. So just for purposes of
18 clarification, does this letter say anything at all
19 about what the Martinsville Family Pharmacy should
20 do with respect to its business practices?

21 MR. SHKOLNIK: Objection to form.

22 THE WITNESS: Now I'm back to what -- my
23 original thought. What they should do in respect
24 to their business practices, in my opinion, is
25 ensure that they have an adequate system to

1 determine if orders are suspicious.

2 BY MS. ZOLNER:

3 Q. And you're referring again to the
4 paragraph on Page 5922, that first full paragraph
5 that says the registrant shall design and operate a
6 system to disclose to the registrant suspicious
7 orders of controlled substances. The registrant
8 shall inform -- sorry about the interruption. We
9 have a lot of people who are very interested in
10 what you have to say, Ms. Ashley.

11 A. Okay.

12 Q. So I'm looking now at the paragraph that
13 you have pointed out to me. Does this paragraph
14 say anything at all about how the Martinsville
15 Family Pharmacy should design its suspicious order
16 monitoring system?

17 A. How they should design the system, no, it
18 does not.

19 Q. Does it say anything other than what was
20 in that original regulation that we looked at in
21 Exhibit 3 earlier today?

22 A. It does not, no.

23 Q. This language is the same language as we
24 looked at in Exhibit 3 with the Controlled
25 Substances Act language, correct?

1 A. Yes.

2 MR. SHKOLNIK: Objection. Form.

3 MS. BACCHUS: Objection. Asked and answered.

4 BY MS. ZOLNER:

5 Q. I'm sorry. I didn't hear your answer.

6 A. Yes.

7 Q. Does the letter state whether any
8 distributor identified the Martinsville Family
9 Pharmacy as one of the pharmacies to which they had
10 chosen to restrict selling controlled substances?

11 A. No, it does not.

12 Q. We're looking at Page 5922, and the second
13 to last paragraph which begins distributors need to
14 know to whom they are selling controlled substances
15 and clearly know their customer's business
16 practices in order to determine whether or not to
17 ship controlled substances, there's some bolded
18 language, and then it cites back to 21 CFR
19 Section 1301.74(b). The next sentence says since
20 it is not the role of DEA --

21 MR. SHKOLNIK: Could we go slower --

22 MS. ZOLNER: Yes.

23 MS. BACCHUS: -- so we can find out where you
24 are? I'm sorry. Which paragraph? Which page?

25 MS. ZOLNER: I am on Page 5922. I'm in the

1 second to last paragraph before the closing you may
2 obtain additional information paragraph.

3 MR. SHKOLNIK: Thank you.

4 BY MS. ZOLNER:

5 Q. Ms. Ashley, I would specifically like to
6 ask you about the last sentence in the second to
7 last paragraph, which is since it is not the role
8 of DEA to determine to whom a distributor should
9 ship controlled substances, you are encouraged to
10 reach out to your distributor to further discuss
11 this matter. Did I read that correctly?

12 A. Yes.

13 Q. What does that mean to you it is not the
14 role of DEA to determine to whom a distributor
15 should ship controlled substances?

16 MR. SHKOLNIK: Objection for DEA's position on
17 something.

18 THE WITNESS: What it means to me is that the
19 distributor would make the determination of whether
20 or not to ship to that customer.

21 BY MS. ZOLNER:

22 Q. In other words, the DEA is not going to
23 make a decision on when a shipment should or should
24 not be sent?

25 MS. BACCHUS: Objection to form.

1 MR. SHKOLNIK: Objection to form.

2 THE WITNESS: That's my experience and
3 understanding, yes.

4 BY MS. ZOLNER:

5 Q. In your opinion, was DEA leaving a lot of
6 discretion to the distributor?

7 MS. BACCHUS: Objection. You can answer if you
8 have an opinion.

9 THE WITNESS: DEA was leaving all discretion to
10 the distributor --

11 BY MS. ZOLNER:

12 Q. All discretion?

13 A. -- to make the decision to ship or not
14 ship.

15 Q. And I sort of stepped over your testimony
16 there. So could you just say what you said again?
17 I interrupted you.

18 A. DEA was leaving all discretion to the
19 distributor whether or not to ship to a customer.
20 It's their decision.

21 Q. In all instances?

22 A. Yes.

23 Q. You can put that letter aside. I'm going
24 to show you another policy letter.

25

1 (Whereupon, ASHLEY Deposition
2 Exhibit No. 22 was marked for
3 identification.)

4 BY MS. ZOLNER:

5 Q. Ms. Ashley, I'm going to start on 5916,
6 which is the first page of a letter from the NCPA
7 to Joe Rannazzisi dated March 7, 2008. Just for
8 purposes of the record, the NCPA is identified as
9 the National Community Pharmacists Association.

10 Are you on the same page with me?

11 A. Yes.

12 Q. Do you see in the first paragraph where it
13 says the National Community Pharmacists Association
14 represents more than 23,000 independent community
15 pharmacies and their 75 licensed pharmacists and
16 300,000 additional employees across the United
17 States?

18 A. Yes.

19 Q. If you move on to the third -- do you have
20 familiarity with the National Community of
21 Pharmacists Association?

22 A. I don't recall them specifically, no.

23 Q. Okay. In the -- but again, this is
24 another OD policy letter, correct?

25 A. Yes.

1 Q. And you received this letter along with
2 other recipients in the diversion group, correct?

3 A. Yes.

4 Q. Do you have any reason to assume that you
5 wouldn't have read this letter?

6 A. No, I have no reason to assume that.

7 Q. Okay. If you could look in the third
8 paragraph which begins we write, and I'll read that
9 paragraph to you so we all know where I am. We
10 write to express our concern that recent efforts by
11 DEA aimed at pharmaceutical wholesalers and
12 distributors to combat the illicit distribution of
13 controlled substances have had unintended
14 consequences and are harming patient care. The DEA
15 policies result in restricting or preventing
16 pharmacies from obtaining medications for patients
17 with legitimate pain needs.

18 Did I read that correctly?

19 A. Yes.

20 Q. In your view and in your experience with
21 DEA, are DEA policies intended to prevent patients
22 from getting medically necessary medication?

23 A. No.

24 MS. BACCHUS: Objection.

25 THE WITNESS: Sorry. No.

1 BY MS. ZOLNER:

2 Q. If the NCPA believed that the DEA's
3 policies were being implemented in a way that would
4 prevent patients from getting medically necessary
5 medication, would that be a concern to you?

6 MR. SHKOLNIK: Objection.

7 MS. BACCHUS: Objection. Calls for
8 speculation.

9 THE WITNESS: Personally, yes, I would be
10 concerned.

11 BY MS. ZOLNER:

12 Q. And in your role with DEA and specifically
13 with diversion, you were responsible for being
14 concerned if medically necessary treatments were
15 not going to patients, right?

16 MS. BACCHUS: Objection to form.

17 MR. SHKOLNIK: Objection to form.

18 THE WITNESS: Correct. It's part of our
19 mission.

20 BY MS. ZOLNER:

21 Q. Could you explain what you mean by that?

22 A. Part of the mission of the Office of
23 Diversion Control is to ensure an adequate supply
24 of controlled substances are available to meet
25 legitimate medical need.

1 Q. So you would agree it would be worth
2 ensuring that DEA's policies weren't preventing
3 patients from obtaining medically necessary
4 medication?

5 MR. SHKOLNIK: Objection. DEA's policy now?

6 MS. BACCHUS: Objection.

7 MR. SHKOLNIK: This is so far outside of what
8 you said this witness is allowed to testify to.

9 THE WITNESS: It's my understanding of DEA's
10 mission is to ensure.

11 BY MS. ZOLNER:

12 Q. I want to make sure I understand that.
13 It's your understanding that it's DEA's mission to
14 ensure that medically necessary medication goes to
15 patients, correct?

16 A. Yes.

17 Q. To your knowledge, did DEA ever
18 investigate the issue raised in this letter?

19 MR. SHKOLNIK: Objection to form.

20 MS. BACCHUS: Objection. If you know.

21 THE WITNESS: An investigation? I can tell you
22 I've had personal conversations.

23 BY MS. ZOLNER:

24 Q. With the NCPA?

25 A. Not NCPA. With industry. I don't know

1 specifically them, but with industry.

2 Q. Okay. Did you have any discussions with
3 anyone at the NCPA after you received this letter?

4 A. I did not, no.

5 Q. When you say that you've had conversations
6 with industry, what do you mean by that?

7 A. In my career as a diversion investigator,
8 I have had conversations with industry about --
9 it's been brought to my attention that distributors
10 would set arbitrary thresholds. I've had those
11 conversations over the years.

12 Q. I think I understand what you mean, but
13 let me just see if I can unpack that.

14 MR. SHKOLNIK: Was the witness done, or did you
15 just interrupt?

16 BY MS. ZOLNER:

17 Q. I'm sorry. Were you finished? I didn't
18 mean to interrupt you.

19 A. Yes.

20 Q. Okay. I thought you were. I try to be
21 careful about that. Thank you.

22 Let me make sure I can unpack what you
23 just said. You said in my career as a diversion
24 investigator, I have had conversations with
25 industry after it's been brought to my attention

1 that distributors are setting arbitrary thresholds.

2 MR. SHKOLNIK: And she said --

3 BY MS. ZOLNER:

4 Q. I've had --

5 MS. ZOLNER: I'm sorry. Could you please stop
6 interrupting me?

7 MR. SHKOLNIK: You're misreading.

8 BY MS. ZOLNER:

9 Q. I've had those conversations over the
10 years. Are you explaining that in an effort to
11 carry out DEA's mission to make sure medically
12 necessary prescriptions go to patients, you've had
13 conversations with distributors to make sure
14 thresholds are not being arbitrarily set to limit
15 medically necessary prescriptions from making it
16 into the hands of patients?

17 MR. SHKOLNIK: Objection to form.

18 THE WITNESS: No.

19 MR. SHKOLNIK: Misreading what the witness
20 said.

21 BY MS. ZOLNER:

22 Q. I'm not trying to misread or misinterpret
23 what you said. I'm asking you to explain it to me.

24 MS. BACCHUS: I have an objection here. I
25 think we're getting a little far field. Are we

1 talking about the opioids? Are we just talking
2 about in general? Are we talking about quotas? I
3 want to make sure we stay within the Touhy
4 authorization.

5 MS. ZOLNER: Ms. Ashley said that she had
6 conversations over the years to make sure she was
7 carrying out DEA's mission to make sure medically
8 necessary prescriptions were going to patients, and
9 I'm just exploring what she meant by that.

10 THE WITNESS: So in the course of my duties
11 and --

12 MR. SHKOLNIK: Objection to form.

13 THE WITNESS: -- conversations with
14 registrants, I have had registrants raise to me
15 that distributors, and I guess I would be speaking
16 about retail pharmacies. I can't bring up a
17 specific conversation, but I know I've had these
18 conversations where retail pharmacies would bring
19 to my attention that arbitrary thresholds were set
20 by distributors, and they were not able to get the
21 supplies that they needed.

22 BY MS. ZOLNER:

23 Q. Understood. Thank you for that
24 clarification.

25 And just to close the loop on that, after

1 those instances were brought to your attention, did
2 you work with pharmacies or distributors to make
3 sure that those threshold levels were changed?

4 MR. SHKOLNIK: Objection. Form.

5 THE WITNESS: Specifically changing thresholds,
6 no.

7 BY MS. ZOLNER:

8 Q. What did you do?

9 A. I would speak with distributors, and it
10 wouldn't -- I don't want to make it appear that it
11 was based on the conversation I had with one
12 retailer. I went back to what they said to that
13 distributor. It's in various conversations with
14 different registrants. I would explain to the
15 retail pharmacies that DEA is not part of that role
16 to set the threshold. I would explain to the
17 distributors that they are in -- that DEA does not
18 set those limits on the customers that they supply
19 to. So it would be separate conversations, not
20 addressing specific concerns with the -- from
21 registrant to the next registrant on behalf of
22 another registrant.

23 Q. And no specific changes to thresholds
24 either?

25 MR. SHKOLNIK: Objection to form.

1 THE WITNESS: No.

2 BY MS. ZOLNER:

3 Q. Did you say no?

4 A. No.

5 Q. Okay. Let's look at this letter again.

6 If you could now look at the fifth paragraph from
7 the top or the second from the bottom. It has
8 bolded italicized language that begins in the face.

9 A. Uh-huh.

10 Q. Do you see where I am? It says in the
11 face of such sweeping nonspecific directives and
12 also recent DEA closures of wholesale distribution
13 centers in Florida and Washington, it is no
14 surprise that our members report overly broad,
15 uneven and punitive actions by various wholesalers.

16 Did I read that correctly?

17 A. Yes.

18 Q. Were you aware of any other instances
19 where registrants were complaining of the DEA
20 directives being nonspecific?

21 A. I'm not sure what you mean by any other
22 circumstance.

23 Q. Sure. So the NCPA is complaining about
24 nonspecific directives in that paragraph. Do you
25 see that language?

1 A. Yes.

2 Q. Are you aware of any other instances where
3 registrants were complaining about these kinds of
4 nonspecific directives?

5 MR. SHKOLNIK: Objection to form.

6 THE WITNESS: I am aware of registrants
7 complaining about nonspecific directives, but other
8 than this one, I don't know because I don't even
9 recall this one. I know that they've made those
10 complaints.

11 BY MS. ZOLNER:

12 Q. And you're talking about some of the
13 complaints that we've talked about earlier in the
14 day directions needing to be more clear?

15 MR. SHKOLNIK: Objection to form. Misstating.

16 THE WITNESS: No. I'm talking about specific
17 to this issue of the arbitrary thresholds, what
18 he's suggesting in this letter.

19 BY MS. ZOLNER:

20 Q. Okay. If you could flip over to
21 Page 1597, do you see in the middle of the page a
22 sentence that begins we did request?

23 A. Yes.

24 Q. It says we did request that DEA hold a
25 meeting with wholesalers, consumer groups and

1 community pharmacies so that all parties can
2 clearly understand the expectations of DEA and can
3 make every reasonable effort to comply. However,
4 that request was flatly refused by DEA. We were
5 disappointed that the agency is not willing to
6 engage in dialogue with the stakeholders that are
7 being affected by its actions and renew this
8 request for a meeting as soon as possible.

9 Did I read that correctly?

10 A. Yes.

11 Q. Were you aware of the request by the NCPA
12 for a meeting?

13 A. No.

14 Q. Were you aware that this request was
15 refused by the DEA?

16 MS. BACCHUS: Objection. Assumes facts not in
17 evidence.

18 THE WITNESS: No.

19 BY MS. ZOLNER:

20 Q. Based on your review of the letter, is it
21 your understanding that the NCPA was asking for a
22 meeting so they could better understand the DEA
23 expectations?

24 MR. SHKOLNIK: Objection. Speculation what
25 they were thinking.

1 THE WITNESS: I'm sorry. Would you repeat
2 that?

3 BY MS. ZOLNER:

4 Q. Sure. Based on your review of the letter,
5 is it your understanding that the NCPA was asking
6 for a meeting so they could better understand DEA
7 expectations?

8 MR. SHKOLNIK: Same objection.

9 MS. BACCHUS: Objection.

10 THE WITNESS: Yes. From my reading of the
11 letter, that's what they stated, yes.

12 BY MS. ZOLNER:

13 Q. Did the DEA send a response to this
14 letter?

15 MS. BACCHUS: If you know.

16 THE WITNESS: This appears to be the response.

17 BY MS. ZOLNER:

18 Q. Right. I was trying to help you out by
19 telling you it's attached to Exhibit 21. I think
20 this is -- Exhibit 22. Pardon me.

21 So Ms. Ashley, I think you're referring to
22 the document that's part of Exhibit 22 Bates
23 numbered first page 5914. Is that accurate?

24 A. Yes.

25 Q. Can you take a look at that response

1 briefly?

2 A. Okay.

3 Q. You've finished reviewing it?

4 Did the DEA attempt to set up a meeting
5 after sending this letter to your knowledge?

6 MS. BACCHUS: Objection. Form. You can answer
7 if you know.

8 THE WITNESS: I don't know.

9 BY MS. ZOLNER:

10 Q. Is there any mention of the NCPA's request
11 for a meeting in the letter?

12 A. I did not see that, no.

13 Q. Do you know if the DEA addressed the issue
14 of whether it was targeting community pharmacies
15 rather than community and chain pharmacies in this
16 letter?

17 MR. SHKOLNIK: Objection.

18 THE WITNESS: No.

19 MR. SHKOLNIK: Asking to speak for the DEA and
20 what their intention was with this letter, and I
21 think, once again, we were supposing to be
22 directing these witnesses not to be speaking for
23 the DEA.

24 MS. ZOLNER: My question was directly and
25 specifically to Ms. Ashley. In fact, it started

1 with do you know. And again, I would ask for you
2 to refrain from speaking objections. I believe
3 that's the fifth time I've said that during the
4 course of the deposition.

5 MR. SHKOLNIK: Six times.

6 MS. ZOLNER: Thank you for the clarification.

7 BY MS. ZOLNER:

8 Q. I don't know if I had a question pending,
9 but I'll --

10 A. I think your question was did I know. No.

11 Q. Okay. Thank you.

12 Do you know if DEA addressed any of the
13 concerns raised by the NCPA?

14 A. I don't know.

15 Q. Was there any outreach, to your knowledge,
16 to find out what was considered to be nonspecific
17 or unclear to the registrant?

18 A. Any outreach, I don't know.

19 Q. To your knowledge, was there any meeting
20 with the registrants in this letter to try to
21 provide additional clarification?

22 A. I don't know.

23 MR. SHKOLNIK: Objection.

24 BY MS. ZOLNER:

25 Q. Are you aware of a meeting?

1 A. I am not.

2 Q. In this letter, if you turn to Page 2,
3 which is Bates numbered 5915 for the record, the
4 last -- the second to last sentence in this letter
5 says DEA understands the concerns that the NCPA has
6 raised, but is unable to require anything more
7 concerning this matter than what is stated in the
8 Controlled Substances Act and its implementing
9 regulations.

10 Do you see that?

11 A. Yes.

12 Q. Did I read that correctly?

13 A. Yes.

14 Q. Is it your understanding that this means
15 DEA cannot require anything more than what is
16 stated in the CSA and its implementing regulations?

17 MS. BACCHUS: Objection. If you have an
18 understanding, you can answer.

19 THE WITNESS: That's how I understand this
20 sentence, yes.

21 BY MS. ZOLNER:

22 Q. Do you think that that sentence is
23 accurate?

24 MS. BACCHUS: Objection.

25 MR. SHKOLNIK: Objection. Asking for DEA's

1 position and accuracy of a DEA position.

2 BY MS. ZOLNER:

3 Q. Based on your experience in your over
4 35 years of tenure with DEA, do you think that
5 sentence is accurate?

6 MR. SHKOLNIK: Objection. You're asking for
7 interpretation of a DEA statement.

8 MS. BACCHUS: You can answer based on your
9 opinion, your personal opinion if you have one.

10 THE WITNESS: Accurate is not the word I would
11 use. Accurate? Let me see. In my personal
12 opinion, I believe that DEA could have a
13 conversation with NCPA, I guess, would be my
14 response.

15 BY MS. ZOLNER:

16 Q. But as you sit here today, you're not
17 aware of any such --

18 A. I'm not aware that there was one.

19 Q. And in this letter, this letter that went
20 to you, it says DEA understands the concerns that
21 the NCPA has raised, but is unable to require
22 anything more concerning this matter than what is
23 stated in the Controlled Substances Act and its
24 implementing regulations.

25 Based on your 35 plus years of experience

1 with DEA, do you think that's true?

2 MR. SHKOLNIK: Objection to form.

3 MS. BACCHUS: Asked and answered.

4 MR. SHKOLNIK: This letter was not directed to
5 this witness. You're misstating it, and you're
6 asking for an interpretation of what the DEA wrote,
7 which is outside the scope.

8 MS. BACCHUS: I would object again on the
9 grounds of mischaracterization.

10 BY MS. ZOLNER:

11 Q. You can answer the question.

12 A. I would have to say I don't know. I don't
13 know.

14 Q. You don't know one way or another if
15 that's accurate?

16 MR. SHKOLNIK: Objection to form.

17 THE WITNESS: Yeah. I don't know if it's
18 accurate.

19 BY MS. ZOLNER:

20 Q. You can -- would you like a break?

21 A. No. I'm good. Keep moving.

22 (Whereupon, ASHLEY Deposition
23 Exhibit No. 23 was marked for
24 identification.)
25

1 BY MS. ZOLNER:

2 Q. Ms. Ashley, this is Exhibit No. 23. Have
3 you seen this document before?

4 A. It appears that I have. I don't recall
5 specifically, but my name is on it.

6 Q. I'm going to ask you about the middle
7 e-mail in the chain first, and I think you were
8 identifying for the record that you were copied on
9 this document, right, copied on Exhibit 23?

10 A. Yes.

11 Q. This was an e-mail from Scott Garriott to
12 James Portner copying you and Timothy Lenzi,
13 correct?

14 A. Yes.

15 Q. Who is Scott Garriott?

16 A. Scott Garriott is a diversion investigator
17 in the Springfield resident office, Springfield,
18 Illinois.

19 Q. Springfield, Illinois. Who is James
20 Portner?

21 A. James Portner is a group supervisor in the
22 Chicago field division. At the time in 2009, he
23 was Scott Garriott's supervisor.

24 Q. What about Timothy Lenzi?

25 A. Tim Lenzi is another diversion

1 investigator in the Chicago field division.

2 Q. If you look on the second page, which is
3 Bates numbered 6057, the first full sentence says
4 what I took away from the meeting was Smith is
5 trying to comply with the suspicious order
6 requirement of the regulation.

7 Did I read that correctly?

8 A. Yes.

9 Q. And then if you drop down two sentences,
10 the next sentence again begins with the all capital
11 Smith, Smith noted. I'm going to the next Smith
12 sentence. Smith admitted there has been
13 difficulties in implementing other aspects of the
14 suspicious order system. In part, this is due to a
15 lack of direction as to what DEA defines as due
16 diligence, including conflicting examples provided
17 by DEA representatives at a DEA conference and what
18 knowing your customer really encompasses.

19 Did I read that correctly?

20 A. Yes.

21 Q. What was your understanding at DEA as to
22 how due diligence was being defined?

23 A. Are you speaking back in this 2009
24 circumstance or just my understanding in general?

25 Q. Your understanding in general first.

1 MR. SHKOLNIK: Objection.

2 THE WITNESS: My understanding in general is
3 that a registrant, a distributor in this case,
4 would look at all the information that they
5 obtained from a customer in order to determine if
6 they should be a customer and if they should supply
7 them with controlled substances.

8 BY MS. ZOLNER:

9 Q. Okay. Do you know if that's -- and I know
10 we just talked about due diligence. Generally due
11 diligence, you clarified if I was asking about due
12 diligence at the time this document was created in
13 the 2009 time frame.

14 Is there a different way that you would
15 define due diligence as of the 2009 time period?

16 A. A different way?

17 MR. SHKOLNIK: Objection to form.

18 THE WITNESS: No. I think what's already
19 published is...

20 BY MS. ZOLNER:

21 Q. Do you know if due diligence is codified
22 anywhere?

23 A. No.

24 Q. Is it part of the definition of the
25 Controlled Substances Act?

1 A. Due diligence is it? I don't -- I don't
2 know if it's in the Controlled Substances Act. I
3 believe it is, but if it's defined there, I don't
4 know.

5 Q. Do you want to go back and look at
6 Exhibit 3? Would that help?

7 A. Oh, under the suspicious order. I'm
8 thinking of CSA, the Controlled Substances Act.
9 That's the regulation, not the act --

10 Q. Okay.

11 A. -- that you showed me.

12 Q. So if we look at the act under Exhibit 3,
13 is due diligence part of the Controlled Substances
14 Act?

15 MS. BACCHUS: Excuse me. Exhibit 3 is not the
16 act.

17 MS. ZOLNER: I'm sorry. You're right.

18 BY MS. ZOLNER:

19 Q. Is it explained in the federal regulation,
20 Exhibit 3?

21 MR. SHKOLNIK: Objection to form. This has now
22 become a conversation. There's no question.

23 THE WITNESS: Is due diligence explained in the
24 what? I'm sorry.

25

1 BY MS. ZOLNER:

2 Q. In the federal regulation.

3 MR. SHKOLNIK: Objection to form.

4 THE WITNESS: No.

5 BY MS. ZOLNER:

6 Q. From your perspective when we look back at
7 Exhibit 23, what does knowing your customer mean in
8 this sentence?

9 MS. BACCHUS: Objection. If you know.

10 MR. SHKOLNIK: Objection. This is asking about
11 a specific inquiry from a specific registrant and
12 her interpretation.

13 MS. ZOLNER: Your speaking objection is noted.

14 MR. SHKOLNIK: Thank you. Is that eight?

15 THE WITNESS: Are you asking me what this
16 investigator meant when he used the term here? I'm
17 not --

18 BY MS. ZOLNER:

19 Q. Yes. From your perspective, what does
20 know your customer mean in this sentence? What
21 would it require?

22 MS. BACCHUS: Same objection to form. Whether
23 you have personal knowledge. If you do, you can
24 answer.

25 THE WITNESS: It wouldn't be from me recalling.

1 It would be from me reading this in front of me
2 today, and my opinion would be that H.D. Smith was
3 not clear on what know your customer means.

4 BY MS. ZOLNER:

5 Q. Do you know if DEA provided any guidance
6 to Smith about what that term means?

7 MS. BACCHUS: Objection. Vague.

8 THE WITNESS: Provided guidance? I'm aware of
9 discussions between Scott Garriott and H.D. Smith.
10 When you say provided guidance, I'm not sure if you
11 just mean discussions. I'm aware of that.

12 BY MS. ZOLNER:

13 Q. But you're not aware of any guidance that
14 was provided?

15 MR. SHKOLNIK: Objection about --

16 MS. BACCHUS: Objection. Asked and answered.

17 MR. SHKOLNIK: Objection to inquiry into a
18 specific investigation regarding H.D. Smith and
19 what an investigator spoke about and what guidance
20 they gave.

21 BY MS. ZOLNER:

22 Q. I'm sorry. Was this, in your view, an
23 investigation?

24 A. I recall an investigation, yes.

25 Q. So I just want to understand your

1 testimony. Is it your testimony that this e-mail
2 is describing an investigation of H.D. Smith and
3 H.D. Smith's request for guidance during the
4 occurrence of that investigation?

5 A. No, it's not my understanding that this
6 e-mail is describing an investigation.

7 Q. Okay.

8 MS. BACCHUS: To the extent it is describing an
9 investigation, she's not authorized to talk about
10 it.

11 MS. ZOLNER: Understood. And that's why I was
12 trying to clarify because this was a document that
13 was produced by DEA. It was not my understanding
14 that it was an investigation. Plaintiff's counsel
15 made that objection, and I wanted to make sure I
16 wasn't going into territory where I shouldn't be
17 asking questions.

18 BY MS. ZOLNER:

19 Q. So to your knowledge, this was not an
20 investigation of H.D. Smith. This was a request
21 from H.D. Smith asking for additional guidance; is
22 that correct?

23 A. No. To my knowledge, this is a summary of
24 a meeting that Scott Garriott and Tim Lenzi
25 attended. These are their notes.

1 Q. And during -- in this summary of this
2 meeting, is it accurate to say that H.D. Smith was
3 complaining that it was getting conflicting
4 guidance from DEA?

5 A. From reading this, this was Scott
6 Garriott's impression, yes.

7 Q. Okay. Did you ever have discussions with
8 anyone at DEA regarding registrant reports of
9 conflicting guidance or conflicting examples being
10 given by DEA representatives?

11 A. Did I have discussions with anyone --

12 Q. Yes.

13 A. -- at DEA that registrants felt they were
14 getting conflicting guidance?

15 Q. Exactly.

16 MR. SHKOLNIK: Objection to form.

17 THE WITNESS: Yes.

18 BY MS. ZOLNER:

19 Q. To your knowledge, did DEA do any
20 follow-up to find out whether there were
21 conflicting examples provided by DEA
22 representatives at the DEA conference that was
23 referenced in this e-mail?

24 MS. BACCHUS: Objection. Vague.

25 THE WITNESS: I do not know.

1 BY MS. ZOLNER:

2 Q. You don't one way or another?

3 A. I do not.

4 Q. You can put this aside.

5 MS. ZOLNER: Do you know how long I've been
6 going?

7 THE VIDEOGRAPHER: About an hour and a half
8 total.

9 MR. SHKOLNIK: If we could take a stretch right
10 now, please, before we get to the next document.

11 MS. ZOLNER: Sure. Can we take a quick break?

12 THE WITNESS: Sure.

13 THE VIDEOGRAPHER: We are off the record at
14 3:56 p.m.

15 (Whereupon, a short break was
16 taken.)

17 THE VIDEOGRAPHER: We are back on the record at
18 4:14 p.m.

19 (Whereupon, ASHLEY Deposition
20 Exhibit No. 24 was marked for
21 identification.)

22 BY MS. ZOLNER:

23 Q. Ms. Ashley, I am going to hand you what is
24 Exhibit 24. I'm just going to ask you about the
25 top e-mail to you from Roxanne Peterson.

1 A. Okay.

2 Q. You've had a chance to read it?

3 A. Yes.

4 Q. So Roxanne Peterson, who is Roxanne
5 Peterson?

6 A. Roxanne Peterson is a diversion
7 investigator in the Merrillville resident office
8 today. At the time she was a group supervisor in
9 the -- I think she was in Indianapolis 2010. No.
10 Maybe she was in the Chicago division. No. She
11 was in Indianapolis.

12 Q. Where is Merrillville?

13 A. Merrillville resident office,
14 Merrillville, Indiana.

15 Q. Did you work with Roxanne Peterson when
16 she worked as a diversion investigator in the
17 Merrillville office?

18 A. Yes.

19 Q. And she sent you this e-mail on November
20 the 2nd, 2010. The subject is Re diversion
21 investigator opportunity, correct?

22 A. Yes.

23 Q. Roxanne writes at least with DEA, we
24 learned that you don't have to do a blessed thing,
25 and you'll still have a job. If I've learned

1 nothing else from being in Indy, it is that. Here
2 all these 20 plus years I did my job because I
3 thought I had to, and here all along I didn't. I
4 could have done nothing and still got promoted.
5 While I am always a day late and dollar short,
6 thanks anyway.

7 Did I read that correctly?

8 A. Yes.

9 Q. Do you know what Roxanne meant by at least
10 with DEA, we've learned that you don't have to do a
11 blessed thing and you'll still have a job?

12 A. I wouldn't interpret it any further. I
13 think she meant what she said.

14 Q. Was Roxanne Peterson a friend of yours?

15 A. She is a friend of mine, yes.

16 Q. Was she frustrated with her experience as
17 a diversion employee with DEA?

18 MR. SHKOLNIK: Objection.

19 MS. BACCHUS: Objection. Calls for
20 speculation.

21 THE WITNESS: From what I recall from this
22 circumstance, yes, she was very frustrated.

23 BY MS. ZOLNER:

24 Q. What did she tell you?

25 A. At the time --

1 MR. SHKOLNIK: Objection.

2 MS. BACCHUS: Objection.

3 THE WITNESS: I have to ask you a question.

4 MS. BACCHUS: One second. Objection. This is
5 outside the scope of her Touhy authorization, and I
6 don't believe that she is authorized to testify
7 about that.

8 MS. ZOLNER: Are you instructing her not to
9 testify on this document?

10 MS. BACCHUS: Yes, I am.

11 BY MS. ZOLNER:

12 Q. I assume you're taking your counsel's
13 advice?

14 A. Yes.

15 Q. If you could look in your pile of
16 documents at Exhibit No. 7, this was a document
17 that Mr. Nicholas explored with you this morning,
18 and I would like you to look at the page with the
19 Bates number 4953. There's a longer number, but
20 I'm just reading the last four digits.

21 MR. SHKOLNIK: Was that No. 7 you said?

22 MS. ZOLNER: It was Exhibit 7, yes.

23 BY MS. ZOLNER:

24 Q. You let me know when you get there.

25 A. Okay.

1 Q. And I'm going to ask you a couple
2 questions about the second page. The last four
3 numbers are 4953, but before we get there, when you
4 acted as diversion program manager in the diversion
5 control division of DEA, how many diversion
6 investigators were in your department?

7 A. I'm sorry. In which role? I'm sorry.

8 Q. When you were working as a diversion
9 program manager.

10 A. I recall there being 48.

11 Q. What about at the time when you made this
12 presentation as associate deputy assistant
13 administrator of DEA Office of Diversion Control in
14 October of 2016, do you recall how many diversion
15 investigators you had at the time?

16 A. So at this time I was deputy assistant
17 administrator. If we're speaking about direct
18 reports, there were five.

19 Q. Five? Let me ask you about a specific
20 item that's on this summary on Exhibit 7. Do you
21 see where it has No. 2(i) for context, there are
22 now approximately 500 diversion investigators, and
23 then in parentheses, it says positions allotted
24 equals approximately 600?

25 A. Uh-huh.

1 Q. Does that mean there was room to add 100
2 additional diversion investigators?

3 A. Yes.

4 Q. Does that refresh your recollection as to
5 the number of diversion investigators as of October
6 of 2016?

7 A. Yes.

8 Q. Was 500 diversion investigators a bigger
9 number or a smaller number than in years past?

10 A. 500 investigators, to my knowledge, it's
11 pretty consistent. We pretty much flexed around
12 500.

13 Q. Do you have an understanding as to why --
14 do you have an understanding as to what it means to
15 say positions allotted equals 600, approximately
16 600?

17 MS. BACCHUS: Objection. This is beyond the
18 scope of what she's authorized to testify to. I'm
19 going to instruct her not to answer unless you can
20 tell me what provision --

21 MS. ZOLNER: Sure. The reason I'm asking this
22 question, this, to me, is -- under the Touhy
23 authorization that was marked earlier as Exhibit 1,
24 this goes to No. 2, your general duties in your
25 former position as the acting assistant

1 administrator for the Office of Diversion Control.
2 This is summarizing a presentation that she made in
3 that role in giving information about the number of
4 investigators.

5 It also goes to her personal recollection
6 of advice that was given to manufacturers and
7 distributors of opioids during her tenure in this
8 office because this presentation talks a lot about
9 the registrant update, which was an update given to
10 manufacturers and distributors.

11 MS. BACCHUS: In response to that, I have to
12 first say that this is a summary prepared by
13 someone else, not her summary. She has not
14 testified that she made these statements as is
15 written there. And second, regarding her general
16 duties, if she says she supervises the
17 investigators or she had an X number of
18 investigators, she's already given you what her
19 general duties are. In terms of just talking about
20 talking points of how many investigators are around
21 and there, that's not part of her general duties.

22 MS. ZOLNER: I think it also goes to her
23 general employment history with the DEA, which is
24 No. 1, but if you're instructing her not to answer
25 that question, I'd like some clarification in terms

1 of what you will allow me to ask her in terms of
2 the size and recruitment of investigators during
3 her tenure with DEA.

4 MS. BACCHUS: Well, I don't think that she can
5 answer in terms of size and recruitments. If you
6 want to know if she was responsible for hiring,
7 that's a question you can ask her, but in terms of
8 her addressing this particular document, I don't
9 think it's been established that this is exactly
10 what she said.

11 MS. ZOLNER: I was actually asking her if this
12 comported with her recollection. How about if we
13 do this. I'll -- let me ask her a couple more
14 questions, and then if you have objections, I'm
15 sure you'll let me know.

16 BY MS. ZOLNER:

17 Q. Just to take a step back, I think you
18 testified that 500 diversion investigators was at
19 or around the number of diversion investigators
20 that were working in the Office of Diversion
21 Control during your tenure with the DEA. Is that
22 accurate?

23 A. Yes, for a number of years I'd say. Yes.

24 Q. In your employment history with DEA, did
25 you have knowledge as to whether there was budget

1 for hiring of additional diversion investigators?

2 A. Did I have knowledge of -- there were
3 periods when I did, yes.

4 Q. And do you know if DEA had the budget to
5 hire an increased number of diversion
6 investigators?

7 MS. BACCHUS: Objection. Vague.

8 THE WITNESS: I know that it changed year to
9 year.

10 BY MS. ZOLNER:

11 Q. To your knowledge based on your employment
12 history with the DEA, was it difficult to hire
13 diversion investigators?

14 A. In my opinion, yes.

15 Q. Why?

16 A. It was difficult because of the
17 requirements, background investigations, budgetary
18 constraints, the relocation policy. There are
19 various reasons. Sometimes folks just didn't want
20 to move when we hired, and we need them in specific
21 areas. So it was a challenge, yes.

22 Q. Based on your experience and your opinion,
23 did DEA do enough to recruit and hire additional
24 diversion investigators?

25 MR. SHKOLNIK: Objection.

1 MS. BACCHUS: Objection. I'm going to instruct
2 her not to answer. That's not within the scope of
3 the Touhy authorizations.

4 BY MS. ZOLNER:

5 Q. Are you going to take your counsel's
6 advice?

7 A. Yes.

8 Q. Based on your employment history and your
9 supervising authority, do you know why there was a
10 delta between the number of diversion investigators
11 and the positions allotted in 2016 meaning a delta
12 between the 500 diversion investigators and the 600
13 positions allotted?

14 MS. BACCHUS: Objection. That's beyond the
15 scope of the Touhy authorization. I'm instructing
16 the witness not to answer.

17 THE WITNESS: I'm not going to answer.

18 BY MS. ZOLNER:

19 Q. You're taking your counsel's advice?

20 A. Yes.

21 Q. When it comes to combatting diversion,
22 have you ever heard it said in your experience with
23 DEA that DEA wanted to arrest its way out of the
24 problem?

25 MR. SHKOLNIK: Objection.

1 MS. BACCHUS: Objection.

2 THE WITNESS: No.

3 BY MS. ZOLNER:

4 Q. You haven't heard that phrase before?

5 A. I've heard a similar phrase, not that one.

6 Q. What phrase have you heard that's similar?

7 A. DEA cannot arrest their way out of the
8 problem.

9 Q. In your experience, did you think that DEA
10 was trying to arrest its way out of the problem of
11 diversion?

12 MS. BACCHUS: Objection. That's beyond the
13 scope of the Touhy authorization. I'm going to
14 instruct the witness not to answer.

15 BY MS. ZOLNER:

16 Q. You're going to take your counsel's
17 advice?

18 A. Yes.

19 Q. I know that seems formulaic, but it's part
20 of what I'm required to do.

21 MS. ZOLNER: Well, I disagree with whether
22 these are issues that are within the scope of the
23 Touhy request, but it doesn't make any sense to
24 take up your time or your counsel's time debating
25 these things on the record. I'll reserve all

1 rights not just with respect to the topics that I
2 was not allowed to explore today, but also with
3 respect to a number of documents that you don't
4 know anything about that were clawed back prior to
5 your deposition today. Those documents were clawed
6 back last week, and there have been additional
7 documents.

8 So I'll turn this over to other counsel
9 who will continue the questioning again just
10 reserving rights to explore those at another time
11 if and when necessary. Thank you. Thanks for your
12 time.

13 THE VIDEOGRAPHER: We are off the record at
14 4:27 p.m.

15 (Whereupon, a short break was
16 taken.)

17 THE VIDEOGRAPHER: We are back on the record at
18 4:31 p.m.

19 MR. SCHUTTE: Good afternoon, Ms. Ashley. My
20 name is Scott Schutte. I represent Rite Aid.

21 EXAMINATION

22 BY MR. SCHUTTE:

23 Q. And let me apologize in advance because in
24 the interest of time, I'm going to be sort of
25 jumping around from topic to topic hopefully to

1 move through things rather quickly.

2 (Whereupon, ASHLEY Deposition
3 Exhibit No. 25 was marked for
4 identification.)

5 BY MR. SCHUTTE:

6 Q. First topic I want to ask you about is
7 let's start with a document we've marked as
8 Exhibit 24, which was produced in native format by
9 the DEA, DEA 1429. First page has the title Office
10 of Diversion Investigator.

11 MR. SHKOLNIK: I don't think I have an exhibit.

12 BY MR. SCHUTTE:

13 Q. Let me start that over.

14 Ms. Ashley, we've marked as Exhibit 25 a
15 document that was produced by the DEA in native
16 format, DEA 1429. It's a PowerPoint dated
17 November 14, 2014 with your name in the lower left
18 corner. Do you see that?

19 A. Yes.

20 Q. Do you have any recollection of the
21 audience to whom this PowerPoint was given?

22 A. I don't. I was hoping it would be on
23 here, but I don't recall.

24 Q. Okay. If you'll turn to the second page
25 of Exhibit 25, which is a document or, excuse me, a

1 page that's titled Mission, do you see that?

2 A. Yes.

3 Q. It says the mission of the Office of
4 Diversion Control is to prevent, detect and
5 investigate the diversion of pharmaceutical
6 controlled substances and listed chemicals for
7 legitimate channels of distribution while ensuring
8 an adequate and uninterrupted supply of controlled
9 substances to meet legitimate medical commercial
10 and scientific needs.

11 Do you see that?

12 A. Yes.

13 Q. Did I read that correctly?

14 A. Yes.

15 Q. And is that, as of November 14, 2014, what
16 you personally understood to be the mission of the
17 Office of Diversion Control?

18 A. Yes.

19 Q. Now, when Ms. Zolner was asking you some
20 questions a few minutes ago about that Martinsville
21 pharmacy, you made a reference to the mission of
22 the Office of Diversion Control?

23 A. Yes.

24 Q. Is this Page 2 of Exhibit 25 the same
25 mission you were referring to there?

1 A. Yes.

2 Q. Will you agree, based on your 35 years of
3 experience at the DEA, that what the Office of
4 Diversion Control is attempting to do is, on one
5 hand, minimize the amount of diversion that occurs
6 while at the same time ensuring that folks who need
7 opioids or other controlled substance can get them?

8 A. I agree with that.

9 Q. Would you also agree that to the extent
10 that diversion efforts are, I think to use your
11 words, arbitrary, which I think was the term you
12 used in connection with the Martinsville Pharmacy
13 testimony. To the extent that the efforts at
14 diversion control are increased, that could have an
15 effect of making opioids available to fewer folks
16 who need them?

17 MR. SHKOLNIK: Objection to form.

18 MS. BACCHUS: I'm going to object to form.

19 MR. SHKOLNIK: And personal opinion.

20 THE WITNESS: Yeah, it's my personal opinion,
21 but I do not agree that they are restrictive enough
22 that it wouldn't allow for persons to get
23 controlled substances if they need it.

24 BY MR. SCHUTTE:

25 Q. Perhaps I misunderstood your testimony

1 about the Martinsville document. I understood your
2 testimony to be that there would be a concern on
3 your part, I'm not asking for the DEA, concern on
4 your part if a distributor was using suspicious
5 monitoring practices that were arbitrary or so
6 restrictive that made it impossible for their
7 customers to be able to get the controlled
8 substances that they needed to distribute to their
9 customers.

10 Did I misunderstand your testimony?

11 A. Yes. What I was attempting to convey is
12 that I would be concerned that a registrant felt
13 that way. I don't believe that the regulations
14 restrict so much that they would not allow
15 controlled substance, but I would be concerned that
16 a registrant felt that way.

17 Q. And I think, perhaps, my questions aren't
18 clear, so let me try this again.

19 We looked at the mission, which is
20 balancing the need to minimize diversion with the
21 need to make sure that folks who need controlled
22 substances can get them. In your experience at the
23 DEA for 35 years, was it your concern that if
24 either the DEA or the registrants who were trying
25 to comply with the DEA regulations became so

1 restrictive in an effort to avoid diversion, that
2 it could impact the amount of controlled substances
3 could get to the people who actually needed them?

4 A. Would I be concerned if they did?

5 Q. Yes.

6 A. If they did, I would be concerned, yes.

7 Q. In your experience, did you ever see that
8 happen?

9 A. No.

10 Q. You testified earlier today -- I'm
11 changing subjects now.

12 You testified earlier today that when you
13 came to headquarters, I think, in 2015 and began
14 working with -- working at headquarters, that there
15 were some initiatives. I don't think you agreed
16 they had been put on hold, that had been
17 deprioritized compared to other things that you and
18 Mr. Milione then undertook to prioritize again.

19 Do you recall that testimony?

20 A. Yes, I do.

21 Q. And one of those initiatives that you
22 talked about was the distributor initiative?

23 A. Did I?

24 Q. I believe.

25 A. I don't recall. Did we talk about

1 distributors?

2 Q. I believe you used that as an example of
3 one of the things that had been de-emphasized that
4 you then put an emphasis on when you came to D.C.
5 at the headquarters in 2015.

6 MR. SHKOLNIK: Objection. Form.

7 THE WITNESS: I don't recall if we were talking
8 about the distributor initiative.

9 BY MR. SCHUTTE:

10 Q. Let me ask it this way. Can you give us
11 the examples that you can recall, as you sit here
12 today, of initiatives that you said had been
13 de-emphasized that you and Mr. Milione emphasized
14 again starting in 2015?

15 A. I'm thinking about the meetings and having
16 registrants come in and speak to -- we would call
17 them meet and greets. That was just our internal
18 name for them. Registrants would reach out to the
19 front office, and I recall this from working in the
20 policy and liaison section, and I was part of the
21 section that would host the meetings when I was in
22 headquarters from 2004 to 2007. Then I left and
23 went to the field.

24 When I returned, I was told by the staff
25 that was present that those meetings had stopped.

1 They weren't having them, that they weren't doing
2 the meet and greets like we used to. So that's my
3 example.

4 Q. Are there any other examples that you can
5 think of, as you sit here today, of initiatives
6 that had been de-emphasized that you and
7 Mr. Milione began to emphasize again in 2015?

8 A. Yes. The distributor initiative is an
9 initiative that was put on hold or not being done
10 at the time, yeah. Now I remember we did talk
11 about that. We did talk about it.

12 Q. You're making me doubt my note-taking
13 ability. Of course, I was way at the end of the
14 table.

15 So you listed the renewed efforts to
16 comply with requests for meet and greets. You
17 talked about the distributor initiatives. Were
18 there any other initiatives that had been
19 de-emphasized that you began to emphasize again in
20 2015?

21 A. I can't think of one at this time.

22 Q. Okay. Thank you.

23 I believe you also testified today that
24 the distributor initiative had been, to your
25 knowledge, de-emphasized somewhere in the ballpark

1 of 2013. Do you recall that?

2 A. Yeah. Yeah.

3 Q. Prior to the point that the distributor
4 initiative was de-emphasized, who was that
5 distributor initiative targeted at? What types of
6 distributors?

7 A. They were speaking to -- the idea was to
8 speak to all distributors. So it wasn't
9 distributors for -- primarily at the top of the
10 list would be those who distributed Schedule II
11 controlled substances, narcotic controlled
12 substances, but the goal was to visit all
13 distributors of controlled substances.

14 Q. Did you -- did you know whether the DEA
15 succeeded in speaking to all distributors before
16 the distributor initiative was put on hold in 2013?

17 A. I know that they had not by March of 2018.

18 Q. Do you recall whether Rite Aid was a
19 distributor who had been spoken to by the DEA
20 before the distributor initiative was put on hold
21 in 2013?

22 A. I don't know.

23 Q. Do you know whether Walmart was such a
24 distributor?

25 A. I don't know.

1 Q. What about CVS?

2 A. I don't know.

3 Q. And what about Walgreens?

4 A. I don't know.

5 Q. Okay. Thank you.

6 I want to change topics again and talk
7 about a subject we've been talking about much of
8 the day, which is the implementing regulation.

9 As I understood your testimony,
10 Ms. Ashley, your testimony is that the CSA and the
11 implementing regulation was clear to you throughout
12 your tenure at DEA?

13 A. I felt comfortable, yes.

14 Q. Is it also fair -- my understanding of
15 your testimony, is it a fair summary that
16 throughout your tenure at DEA, you understood that
17 distributors were asking DEA for guidance because
18 the implementing regulations was not crystal clear
19 to them?

20 A. Correct. They did express that.

21 Q. And while you were at DEA, and let's focus
22 on the time period between 2007 and the time you
23 retired in March of 2018, did you consider it to be
24 within the scope of your job either when you were
25 supervising diversion investigators or when you

1 were in headquarters to try to help distributors
2 understand what their obligations were under the
3 implementing regulations?

4 A. I did consider that to be within the scope
5 of my job.

6 Q. And did you try to do that whenever you
7 could?

8 A. Yes, I did.

9 Q. Okay. Now, if I could ask you to pull out
10 of your pile of documents Exhibit 4, which is
11 something we looked at earlier today. That's that
12 e-mail about Kroger.

13 MR. SCHUTTE: Can we go off record for a moment
14 while we identify that?

15 THE VIDEOGRAPHER: We're off the record at
16 4:44 p.m.

17 (Whereupon, a short break was
18 taken.)

19 THE VIDEOGRAPHER: We're back on the record at
20 4:44 p.m.

21 BY MR. SCHUTTE:

22 Q. Ms. Ashley, now that you have Exhibit 4 in
23 front of you, and I know counsel asked some
24 questions about this earlier today, your testimony
25 is that as of February 24th of 2010 when you wrote

1 this e-mail asking Ms. Boockholdt whether, quote,
2 you are -- are you asking that the field contact
3 registrants and tell the registrant that they
4 cannot fill an order based solely in our review of
5 a suspicious order report, end quote, is it your
6 testimony that when you asked that question, you
7 knew what the answer to that question was?

8 MR. SHKOLNIK: Objection to the form.

9 THE WITNESS: I had a personal understanding of
10 what the answer was, yes.

11 BY MR. SCHUTTE:

12 Q. And your personal understanding was what?

13 A. That we do not tell registrants that they
14 cannot ship an order, especially solely on a
15 suspicious order report and no other information.

16 Q. Because I think as you told Ms. Zolner a
17 few minutes ago, the decision to ship or not ship
18 is solely in the discretion of the distributor?

19 A. Yes.

20 Q. Why were you asking the question then to
21 headquarters?

22 A. I was -- I don't recall this specifically,
23 but the way I'm reading it is I'm prodding Barbara
24 to respond to tell me did something change.

25 Q. And did you get a response to this e-mail

1 that you recall?

2 A. I don't recall.

3 Q. Was part of the reason that you wrote this
4 because -- this e-mail marked as Exhibit 4 because
5 you had concerns that there was a disconnect
6 between headquarters and the field as to what the
7 regulation was?

8 MR. SHKOLNIK: Objection to form.

9 MS. BACCHUS: Objection. Form.

10 THE WITNESS: I don't know if that -- I can't
11 say that that is what I was thinking.

12 BY MR. SCHUTTE:

13 Q. Is it possible that's what you were
14 thinking?

15 MR. SHKOLNIK: Objection.

16 MS. BACCHUS: Objection. Form.

17 MR. SHKOLNIK: Speculative.

18 MS. BACCHUS: Asked and answered.

19 THE WITNESS: Is it possible? I have to say I
20 don't think so. I wanted to know what she thought.

21 BY MR. SCHUTTE:

22 Q. So was it in your head when you wrote this
23 e-mail on February 24th of 2010 that it could be
24 the case that Ms. Boockholdt had a different
25 understanding of the reg than you did?

1 A. That's what I was trying to elicit from
2 her, you know, do you have a different
3 understanding than me.

4 Q. But you don't recall what her response
5 was?

6 A. I don't.

7 Q. And again, at this time you had already
8 understood that distributors had questions about
9 what the directive was under the regulation?

10 A. Yes.

11 Q. Okay. And then on the last sentence in
12 that same paragraph where you asked Ms. Boockholdt
13 the question on what authority do we have to tell a
14 registrant that they cannot fill an order absent an
15 investigation and clear violations, first,
16 Ms. Ashley, did you get an answer to that question?

17 A. I do not recall getting an answer.

18 Q. Second is why -- did you have a personal
19 opinion as of February 24th of 2010 as to whether
20 the DEA had authority to tell a registrant that
21 they cannot fill an order absent an investigation
22 and clear violation?

23 A. No. My question was yeah, would we have
24 that authority. Wait a minute. Let me read this
25 again. What I'm thinking here, in order for DEA to

1 tell a registrant that they cannot ship an order,
2 there would have to be some sort of investigation
3 or we would have identified a violation.
4 Otherwise, the discretion to ship is solely on the
5 registrants.

6 Q. And were you asking that question of
7 Ms. Boockholdt on February 24, 2010 because you
8 were not sure what her answer would be to that
9 question?

10 MR. SHKOLNIK: Objection.

11 MS. BACCHUS: Objection. Form.

12 MR. SHKOLNIK: Speculation.

13 BY MR. SCHUTTE:

14 Q. Let me rephrase the question.

15 When I asked about the prior sentence, you
16 said you were, I hope I'm not mischaracterizing
17 your testimony, prodding her to answer so you
18 understood her position. Do I have that right?

19 A. I would agree with that.

20 Q. Is that what you were also doing with this
21 last question? You were prodding Ms. Boockholdt to
22 tell you what the answer was so you made sure that
23 you were on the same page as headquarters?

24 MS. BACCHUS: Objection. Form.

25 MR. SHKOLNIK: Objection. Speculation.

1 THE WITNESS: I would agree that I was prodding
2 her.

3 BY MR. SCHUTTE:

4 Q. I'm going to change subjects slightly here
5 and talk about a different aspect of the
6 implementing regulation. As I've understood your
7 testimony today, distributors, in your view, have
8 to look at a variety of factors in making a
9 decision whether or not to ship, and I believe you
10 said that it can vary from situation to situation
11 what it means -- let me pull out my document here
12 what it would mean for an order to be unusual size.
13 I believe I've understood your testimony to be that
14 that varies from situation to situation?

15 A. Yes.

16 Q. Similarly, whether an order deviates
17 substantially from a normal pattern would vary from
18 situation to situation?

19 A. Yes.

20 Q. And orders of unusual frequency would vary
21 from situation to situation?

22 A. Yes.

23 Q. And all of these would be based on factors
24 that were specific to that distributor and the
25 facts the distributor was looking at?

1 A. Yes.

2 Q. Would one of the factors that the
3 distributor should take into account is the
4 customer that's placing the order?

5 A. Yes.

6 Q. And how, in your view, as a 35-year
7 employee of DEA would a distributor take into
8 account its customer in determining whether an
9 order was suspicious?

10 A. They -- in my experience, what the
11 distributor does is they get very specific
12 information from their customer like their tax ID
13 number, their location, the orders that they may
14 want from the distributor, what they want to be
15 supplied. The location is a big factor. It tells
16 the population. So they ask very specific
17 questions who their customer base is.

18 Q. When you say who their customer base is,
19 do you mean the -- go ahead. What do you mean by
20 their customer base?

21 A. The -- say the retail pharmacy's customer
22 base.

23 Q. Now, you understand -- I think I've told
24 you I represent Rite Aid.

25 A. Uh-huh.

1 Q. That's a yes?

2 A. Yes.

3 Q. Thank you.

4 And you understand or is it your
5 understanding that Rite Aid distributes only to
6 Rite Aid pharmacies?

7 A. That's what I recall.

8 Q. Do you understand that Rite Aid does not
9 distribute to internet pharmacies or pharmacies
10 that aren't affiliated with Rite Aid?

11 MR. SHKOLNIK: Objection.

12 MS. BACCHUS: Objection. If you know.

13 THE WITNESS: I don't know that for certain.

14 BY MR. SCHUTTE:

15 Q. If it were the case that while during the
16 time period that Rite Aid was distributing
17 controlled substances that Rite Aid only
18 distributed to its own pharmacies, is that a factor
19 that would be appropriate for Rite Aid to take into
20 account when determining whether an order was
21 suspicious or not?

22 MR. SHKOLNIK: Objection to form.

23 THE WITNESS: It's one of the factors, sure.
24 Yes.

25

1 BY MR. SCHUTTE:

2 Q. And that would also be true -- if the same
3 base of the hypothetical was true for CVS and
4 Walmart and Walgreens, would you also agree that
5 the fact that these entities only shipped to their
6 own pharmacies is a factor that should be taken
7 into consideration when determining whether an
8 order is suspicious?

9 A. Yes, I believe that's a factor.

10 Q. And it's also a factor that can be taken
11 into consideration in making a determination
12 whether to ship an order?

13 A. Yes.

14 Q. You testified at some length this morning
15 that when you came to D.C. in, I think it was,
16 September of 2015. Do I have that right?

17 A. Yes.

18 Q. With Mr. Milione, that there was a change
19 in philosophy about interactions between DEA and
20 distributors. Do I have that right?

21 A. Yes.

22 Q. What was the reason for that change?

23 A. One of the reasons was pretty soon after
24 we arrived, we were getting, you know, phone calls
25 e-mails from the registrant community hoping to

1 meet with us and them, the registrant community
2 stating to us that they had not had much
3 engagement. So they were speaking to us directly.
4 So that was a reason.

5 Q. But in prior years, I believe it was your
6 testimony that when those overtures were made, they
7 were not -- the answer was not yes. It was no,
8 we're not going to meet with you?

9 MS. BACCHUS: Objection.

10 MR. SCHUTTE: That's a fair objection. Let me
11 withdraw the question.

12 BY MR. SCHUTTE:

13 Q. What I'm asking you now is not really,
14 Ms. Ashley, what you experienced in terms of
15 questions being asked. I'm asking why it is that
16 you and Mr. Milione decided to meet with
17 distributors when they asked to meet with you when
18 that was not always true in the past? Why did you
19 do it? What did you hope to accomplish?

20 A. We felt that if we communicated better, we
21 could understand each other better, and it would
22 help us to ensure that registrants are in
23 compliance with the controlled substances.

24 Q. It would also ensure that DEA was meeting
25 its mission, which was, on one hand, to get

1 controlled substances to the folks who need them,
2 but at the same time, minimizing diversion?

3 MR. SHKOLNIK: Objection to form.

4 MS. BACCHUS: Objection. Form.

5 THE WITNESS: I would say it would help to
6 accomplish DEA -- yeah, I would, DEA's mission,
7 yes.

8 BY MR. SCHUTTE:

9 Q. And would you agree with me that
10 communications between the Office of Diversion
11 Control and distributors could help the
12 distributors be more effective in minimizing
13 diversion?

14 A. It would help them better understand our
15 regulations, which would, in turn, help minimize
16 diversion.

17 Q. You testified earlier today that it was in
18 the discretion of the distributors to make the
19 decision whether an order was suspicious and
20 whether to ship, correct?

21 A. Yes.

22 Q. Are other aspects of a distributor's
23 efforts to comply with the suspicious order
24 monitoring system also discretionary? For example,
25 the level of recordkeeping done by a distributor,

1 is that something that's discretionary?

2 A. The level of recordkeeping as -- I'm
3 sorry. Only specific to suspicious orders what
4 records they keep?

5 Q. Let's start with that. Is how the records
6 are kept in connection with suspicious order
7 something that's left to the discretion of
8 distributors just as the decision as to whether an
9 order is suspicious or whether an order should be
10 shipped?

11 A. How the records are kept are left to the
12 discretion of the distributor, yes.

13 Q. Is the documentation of a distributor
14 suspicious order monitoring system how it's -- how
15 it is set up and how it's implemented also
16 something that is in the discretion of the
17 distributors?

18 A. Yes.

19 MR. SCHUTTE: Can we go off the record for like
20 two minutes so I can consult with my cocounsel, and
21 I may be finished.

22 THE VIDEOGRAPHER: We're off the record at
23 4:56 p.m.

24 (Whereupon, a short break was
25 taken.)

1 THE VIDEOGRAPHER: We're back on the record at
2 5:01 p.m.

3 BY MR. SCHUTTE:

4 Q. Ms. Ashley, thank you for your patience.
5 I just have a couple more questions.

6 I was asking a series of questions a
7 moment ago about whether things like recordkeeping
8 and documentation of suspicious order monitoring
9 are in the discretion of the distributors, and you
10 said yes. I want to ask the same questions about
11 whether -- how a distributor conducts its due
12 diligence to determine whether an order is
13 suspicious.

14 Is that something that's in the discretion
15 of the distributor?

16 A. How they conduct --

17 Q. The due diligence.

18 A. Yeah.

19 Q. And is how they document -- strike that
20 and start over.

21 Is how a distributor documents the due
22 diligence it conducts, is that also something
23 that's in the discretion of the distributor?

24 A. How they document it? Okay. Ask the
25 question again.

1 Q. Yes, ma'am. Is how a distributor
2 documents the due diligence it conducts something
3 that's in the discretion of the distributor?

4 A. How they document it? How they do it, I'd
5 have to say, yes.

6 Q. Okay.

7 MR. SCHUTTE: How much time do we have on the
8 record?

9 THE VIDEOGRAPHER: You've been on for
10 25 minutes.

11 MR. SCHUTTE: Total.

12 THE VIDEOGRAPHER: Total is five hours and 22
13 minutes.

14 MR. SCHUTTE: So I believe that the defendants
15 have used five hours and 22 minutes, so we'll
16 reserve the additional hour and eight minutes for
17 redirect after plaintiff is finished. Thank you
18 for your time.

19 MR. SHKOLNIK: We have to go off. I need to
20 switch and get documents. If you don't mind, we'll
21 just take 10 minutes.

22 THE VIDEOGRAPHER: We're off the record at
23 5:02 p.m.

24 (Whereupon, a short break was
25 taken.)

1 THE VIDEOGRAPHER: We're back on the record at
2 5:19 p.m.

3 EXAMINATION

4 BY MR. SHKOLNIK:

5 Q. Is it Mrs. Ashley or Ms. Ashley?

6 A. Ms. Ashley.

7 Q. I introduced myself before. My name is
8 Hunter Shkolnik. I'm here as a representative of
9 what we call the Plaintiffs Executive Committee in
10 this litigation. I'm also counsel for Cuyahoga
11 County, which is the first trial, one of the first
12 trials that are going to go forward at the end of
13 the year involving the opioid litigation.

14 I'll try to go through this as quickly as
15 possible. I'm usually -- I can get too fast
16 sometimes. I'm going to take it easy and hopefully
17 get you out of here in less than the time I'm
18 allotted.

19 You were asked some questions just a
20 little while ago by counsel for what I would
21 call -- they refer to themselves as the pharmacies,
22 but I'm referring to them as the chain distributor
23 pharmacies in this case, Rite Aid, Walmart,
24 Walgreens and the like. And they asked you
25 questions if they didn't sell to internet on the

1 internet, if they only distributed to themselves,
2 are these things that should be taken into
3 consideration as part of their due diligence, and I
4 think your answer was well, certainly. Am I
5 correct?

6 MR. SCHUTTE: Object to form.

7 THE WITNESS: I think my answer was yes.

8 BY MR. SHKOLNIK:

9 Q. And the mere fact that they don't sell on
10 the internet or they distribute it to themselves
11 does not relieve them for any of the obligations
12 that they have under the Controlled Substances Act
13 and the regulation promulgated thereunder. Fair
14 statement?

15 MS. ZOLNER: Object to the form.

16 THE WITNESS: That's correct. It doesn't
17 alleviate any obligations.

18 BY MR. SHKOLNIK:

19 Q. And in fact, unlike a distributor, for
20 example, the McKessons, the Cardinal Healths,
21 AmerisourceBergens who don't own the pharmacy,
22 there is no plausible argument that you don't know
23 what's happening at your pharmacy level if you're
24 actually a chain pharmacy distributor. Fair
25 statement?

1 MS. BACCHUS: Object to form.

2 BY MR. SHKOLNIK:

3 Q. Do you want me to read that back?

4 A. Sure.

5 Q. Unlike distributors, for example,
6 McKesson, Cardinal Health, AmerisourceBergen that
7 don't own their own pharmacies, there is no
8 plausible argument that these chain pharmacy
9 distributors can have that they don't know what is
10 going on at the pharmacy level. Is that a fair
11 statement?

12 MS. BACCHUS: Same objection. Object to form.

13 THE WITNESS: It's my opinion that they would
14 know exactly what's going on with their company.

15 BY MR. SHKOLNIK:

16 Q. And I'm just asking about your opinion,
17 and I'm going to phrase my questions that way.

18 In your opinion, as a chain pharmacy
19 distributor, they would have certain obligations to
20 utilize the knowledge at the pharmacy level to help
21 them make decisions regarding due diligence up the
22 chain in distributions. Fair statement?

23 MS. BACCHUS: Objection. Form.

24 MR. DAVISON: Objection.

25 THE WITNESS: It's fair that they have the same

1 obligation, and they would have the information
2 available to them.

3 BY MR. SHKOLNIK:

4 Q. And you were asked questions, I think
5 quite extensively, by counsel earlier about
6 something known as or they refer to as visibility.
7 Someone may not have visibility either downstream
8 or upstream depending upon where they are in this
9 closed system, correct?

10 A. They may not, correct.

11 Q. On the other hand, you were asked
12 questions about chargeback data and purchasing
13 sales data. That would be a way to ensure
14 visibility either upstream or downstream depending
15 upon where you were in the closed chain?

16 MS. ZOLNER: Object to form.

17 MS. BACCHUS: Objection to form.

18 THE WITNESS: Depending on -- I'm sorry.
19 Repeat that.

20 BY MR. SHKOLNIK:

21 Q. If someone is purchasing sales data from
22 the pharmacy level or distribution information,
23 that is just a method to increase visibility at the
24 different levels of the distribution chain,
25 correct?

1 MS. ZOLNER: Objection. Form. Foundation.

2 Vague.

3 THE WITNESS: I agree with that.

4 BY MR. SHKOLNIK:

5 Q. And would you agree -- and I'm asking for
6 your personal opinion on this after 30 years in
7 this field. Would you agree with me that it's the
8 possession of the knowledge, you know, knowing who
9 was buying the pills, where the pills are going,
10 how they're being distributed, if you possess that
11 knowledge, it doesn't make a difference if you're a
12 manufacturer, a distributor or a pharmacy if you
13 possess the knowledge that will allow you to
14 determine whether or not suspicious orders are
15 being filled? It's your obligation under the
16 Controlled Substances Act to act on that. Fair
17 statement?

18 MR. NICHOLAS: Objection to the form.

19 MS. ZOLNER: Objection. Calls for a legal
20 conclusion.

21 MR. STEPHENS: Object to form.

22 BY MR. SHKOLNIK:

23 Q. I'm asking for your personal opinion.

24 A. Personally that would be my expectation.

25 Q. And in fact, over the years that you were

1 with the DEA, and I'm not asking about any
2 investigations you were involved in, you became
3 aware, did you not, that many of the chain
4 pharmacies were the subject of investigations and
5 also settlements with the DEA because they didn't
6 appropriately fulfill their obligations under the
7 control substances act, correct?

8 MS. BACCHUS: Objection. Form.

9 MR. HYNES: Objection.

10 THE WITNESS: I am aware of that.

11 BY MR. SHKOLNIK:

12 Q. I mean, for example, Walgreens,
13 \$80 million fine because they did not comply with
14 their obligations under the act. You're aware of
15 that, correct?

16 MR. STOFFELMAYR: Objection to the form. It
17 was not a fine. It was a settlement.

18 THE WITNESS: I'm aware of the investigation,
19 yes.

20 BY MR. SHKOLNIK:

21 Q. And you're aware they that were -- they
22 decided to settle with the DEA for \$80 million,
23 correct?

24 A. I am aware of that.

25 Q. And you're aware that the agency did an

1 extensive investigation, and there was litigation
2 regarding their actions of not complying with the
3 Controlled Substances Act?

4 MR. STOFFELMAYR: I would object to the form
5 and also object that at this point, this is well
6 beyond the scope of what's within the Touhy letter
7 as to a specific investigation.

8 MS. BACCHUS: And I will object that she cannot
9 testify regarding any specific investigations. To
10 the extent that the matter is public knowledge, she
11 may testify if she knows.

12 THE WITNESS: No.

13 BY MR. SHKOLNIK:

14 Q. Did you know that publicly that there was
15 an investigation of Walgreens, and they settled
16 because of violations of the Controlled Substances
17 Act in monitoring suspicious orders?

18 A. Yes, I did know that.

19 MR. STOFFELMAYR: Objection to the form. Calls
20 for speculation.

21 BY MR. SHKOLNIK:

22 Q. Do you know that McKesson has had
23 settlements for violations of the Controlled
24 Substances Act for failing to honor their
25 obligations under the act? Are you aware of that?

1 MR. EPPICH: Object to the form. Misstates the
2 evidence.

3 BY MR. SHKOLNIK:

4 Q. Publicly aware.

5 A. Publicly aware.

6 MR. EPPICH: Object to the form.

7 BY MR. SHKOLNIK:

8 Q. If I was to list all of the big
9 distributors, we're talking AmerisourceBergen,
10 we're talking Cardinal Health, we're talking
11 McKesson, Walgreens, they're all -- they were all
12 subject to settlements with the DEA because the
13 DEA, and I'm asking for public information, because
14 the DEA found they all violated the Controlled
15 Substances Act, correct?

16 MR. NICHOLAS: Object to the form. Lack of
17 foundation.

18 MS. BACCHUS: I would object to the form and
19 foundation as well.

20 MR. EPPICH: I just want to make clear on the
21 record that one objection is the same objection for
22 all?

23 MR. SHKOLNIK: Absolutely.

24 MR. EPPICH: Thanks.

25

1 BY MR. SHKOLNIK:

2 Q. Am I right?

3 A. I am publicly aware of those -- all of
4 those cases from public information.

5 Q. And let's talk about Purdue Pharma in
6 particular. You're aware publicly, are you not,
7 that they actually plead guilty to felonies with
8 respect to the manner in which they marketed their
9 drug, OxyContin? You're aware of that publicly.
10 Isn't that a fair statement?

11 MS. ZOLNER: Objection. Form. Objection.
12 Scope.

13 MS. MACKAY: Same.

14 THE WITNESS: I have knowledge from public
15 information of the Purdue investigation.

16 BY MR. SHKOLNIK:

17 Q. Executives plead guilty and the company
18 plead guilty to a felony. I'm sorry. The
19 executives plead guilty to felonies, correct?

20 MS. BACCHUS: I'm going to object on the
21 grounds of Touhy. This is getting a little bit
22 beyond the scope of the Touhy.

23 BY MR. SHKOLNIK:

24 Q. All right. So let me just jump ahead
25 then. I'm going to mark as Exhibit No. 26 what

1 I --

2 MR. SHKOLNIK: Just for all counsel, I have a
3 full copy of a document. It's about 140 pages, but
4 I'm only using seven pages of it. I'm going to
5 mark the big document, and I'm going to make copies
6 of the seven pages I'm using. And if anybody needs
7 the rest, you can have it.

8 MR. EPPICH: Can you read off the Bates number
9 for us?

10 MR. SHKOLNIK: I will.

11 MR. EPPICH: Thank you.

12 MR. SHKOLNIK: The Bates US-DEA-00000001, and I
13 didn't -- we didn't show it because it's been
14 redacted as a claw-back document already.

15 MR. NICHOLAS: Could you clarify what you mean
16 when you say it was clawed back, but redacted?

17 MR. SHKOLNIK: I'm saying it's been redacted by
18 DEA.

19 MS. ZOLNER: Do you have a copy of that
20 document?

21 MR. SHKOLNIK: It's coming.

22 MS. BACCHUS: I'm sorry. You said this has
23 been clawed back?

24 MR. SHKOLNIK: Not clawed back. It's been
25 redacted by DEA.

1 MR. EPPICH: Sorry. Was that redaction today,
2 or is that --

3 MR. HYNES: It's been redacted when it was
4 produced originally.

5 MR. SHKOLNIK: It was produced with the
6 redaction.

7 (Whereupon, ASHLEY Deposition
8 Exhibit No. 26 was marked for
9 identification.)

10 BY MR. SHKOLNIK:

11 Q. I've just handed you what's been marked as
12 Exhibit 26 here. It's a document dated November 5,
13 2012, and let me just zoom it in here so the jury
14 will be able to see it. And you'll hear me say
15 things like the jury will be able to see it because
16 this can get presented at trial. This document is
17 something entitled a memorandum, subject, briefing
18 with Actavis Elizabeth, LLC 2012.

19 When you were at DEA, were you aware that
20 there were briefings being done with manufacturers
21 as well as with distributors?

22 A. I don't recall manufacturers. I'm certain
23 of distributors.

24 Q. Here we have what we see is written is a
25 distributor briefing with Actavis Elizabeth, and it

1 says it's written to a Mr. Joseph Rannazzisi,
2 deputy assistant administrator, Office of Diversion
3 Control.

4 Can you tell the jury who Mr. Rannazzisi
5 was in relation -- who he was and where he was in
6 relation to you at DEA over the years?

7 MS. ZOLNER: Objection. Form.

8 THE WITNESS: In 2012 Mr. Rannazzisi was the
9 deputy assistant administrator for the Office of
10 Diversion Control in headquarters Arlington,
11 Virginia. I was in the Chicago field division. I
12 never reported directly to Mr. Rannazzisi, but I
13 was always under the diversion umbrella.

14 BY MR. SHKOLNIK:

15 Q. And at some point, did you move up into a
16 similar position of what Mr. Rannazzisi was?

17 A. Yes.

18 Q. And was that after his retirement from the
19 agency?

20 A. Yes.

21 Q. And just briefly, if you could tell the
22 Court and jury, during the years that
23 Mr. Rannazzisi was in the position as deputy
24 assistant administrator for Office of Diversion
25 Control, did you have a chance to observe the work

1 that he was doing on behalf of DEA?

2 MS. ZOLNER: Objection. Form.

3 THE WITNESS: Specifically, I mean, some --
4 have I seen him -- I've seen him do presentations?
5 I mean, I'm not sure.

6 BY MR. SHKOLNIK:

7 Q. I guess let me rephrase. I'll phrase it
8 differently then.

9 Mr. Rannazzisi was involved in overseeing
10 many aspects of the diversion control office of the
11 DEA, correct?

12 A. Yes.

13 MS. ZOLNER: Objection. Form. Objection.
14 Vague.

15 BY MR. SHKOLNIK:

16 Q. And he was also involved with -- in fact,
17 he was the one who authored various letters to the
18 registrants, one of which we saw here today, a
19 December, I think it was, 2007 letter?

20 A. Yes.

21 Q. And he also wrote a couple other ones that
22 went out to registrants, did he not?

23 MS. ZOLNER: Objection to form.

24 THE WITNESS: Yes.

25

1 BY MR. SHKOLNIK:

2 Q. And specifically those letters to the
3 registrant, what was the purpose of those type of
4 letters to the registrant, from your knowledge
5 being out in the field during those years, when
6 Mr. Rannazzisi, did it?

7 MR. NICHOLAS: Object to the form.

8 MR. EPPICH: Objection. Foundation.

9 MR. NICHOLAS: No foundation.

10 BY MR. SHKOLNIK:

11 Q. If you know.

12 A. My knowledge from receiving the letters
13 and reading them myself was to have the registrants
14 understand DEA's expectation.

15 Q. Was there problems going on around 2005,
16 2006, 2007, to your knowledge, that the DEA was
17 observing with respect to opioid and developing
18 epidemic?

19 MS. ZOLNER: Objection. Form.

20 BY MR. SHKOLNIK:

21 Q. Your own personal knowledge.

22 MS. ZOLNER: Objection. Form. Objection.
23 Compound.

24 MS. BACCHUS: Objection. It's a vague
25 question.

1 THE WITNESS: In my personal experience as an
2 investigator, yeah, there was -- there were issues
3 with a rise in abuse of controlled substances.

4 BY MR. SHKOLNIK:

5 Q. Was there -- from your observation, did
6 the DEA begin to be very concerned and wanted to
7 take some action around that time to see if steps
8 could be taken to try to curb back the problem that
9 was developing?

10 MS. ZOLNER: Objection. Form. Objection.
11 Vague. Objection. Foundation.

12 THE WITNESS: In my experience, that was always
13 the case. I mean, yeah.

14 BY MR. SHKOLNIK:

15 Q. That's a good question. I guess I should
16 have asked that first.

17 While you were with the DEA, what was --
18 you know, from your personal perspective, what was
19 your belief of what you were doing out there in
20 terms of trying to or not trying to avert an opioid
21 epidemic that was developing?

22 MS. BACCHUS: Objection. Form. You can
23 answer.

24 THE WITNESS: My understanding of my
25 responsibility was to engage with the registrant

1 communities, oversee and ensure compliance with the
2 Controlled Substances Act to do the things and
3 address them depending on what they were to ensure
4 that there weren't abuses, misuses and also to
5 ensure that adequate supply was available for those
6 that needed it.

7 BY MR. SHKOLNIK:

8 Q. You were asked questions about the
9 adequate supply, and that was certainly part of
10 what you believed your job was to do, make sure
11 there was adequate supply, correct?

12 A. Yes.

13 Q. Was there a perception -- did you have a
14 perception over the years that there appeared to be
15 developing a disregard for the obligations under
16 the Controlled Substances Act by some of the
17 registrants as this epidemic was developing?

18 MS. ZOLNER: Objection. Form. Objection.
19 Vague.

20 THE WITNESS: I can say that I encountered
21 circumstances where there was disregard, but it --
22 not always.

23 BY MR. SHKOLNIK:

24 Q. But there were times where -- did you,
25 from your observation of what was happening over

1 the years, observe that some of the larger
2 registrants may have been failing to abide by their
3 requirements to prevent diversion?

4 MS. ZOLNER: Objection. Form.

5 BY MR. SHKOLNIK:

6 Q. Just generally speaking.

7 MS. ZOLNER: Objection. Form. Objection.
8 Vague.

9 MS. MCNAMARA: Objection. Foundation.
10 Objection to time.

11 THE WITNESS: In my career, yes, I have
12 experience with registrants not operating in
13 compliance with the Controlled Substances Act.

14 BY MR. SHKOLNIK:

15 Q. From your perspective, was part of your
16 job to do your best to see if you could try to get
17 these registrants to follow the rules and do their
18 job in terms of compliance with the Controlled
19 Substances Act?

20 MS. ZOLNER: Objection. Form. Objection.
21 Vague.

22 THE WITNESS: Part of my job responsibility was
23 to bring the registrant into compliance, yes.

24 BY MR. SHKOLNIK:

25 Q. And certainly the letters issued by

1 Mr. Rannazzisi was one way that you observed DEA as
2 a whole trying to get industry, when I say
3 industry, the registrants, into compliance and to
4 follow the rules?

5 MR. NICHOLAS: Object to the form.

6 MS. MCNAMARA: Objection to form.

7 MR. NICHOLAS: Lack of foundation.

8 MS. BACCHUS: I object to the form of the
9 question.

10 THE WITNESS: Should I answer?

11 BY MR. SHKOLNIK:

12 Q. Yes.

13 A. That's my understanding of the purpose of
14 the letter.

15 Q. This letter we have here is not one of
16 the -- this document here, Exhibit No. 26, is not
17 one of those Rannazzisi letters. Have you ever
18 seen, during the course of your time with DEA,
19 memorandums that were written sort of to the file
20 to the agency describing meetings with registrants?

21 A. Have I? Yes.

22 Q. And we're looking here -- this one talks
23 about it's a briefing -- it's sort of a briefing
24 memo following a meeting with this company,
25 Actavis. Do you know who Actavis was?

1 A. I've heard of them, yes.

2 Q. They were a registrant, were they not?

3 A. Yes, a DEA registrant. Yes.

4 Q. And here it says that on September 12,
5 2012, a meeting was held in Arlington, Virginia at
6 Drug Enforcement Administration headquarters
7 between DEA, Actavis, LLC, and it identifies who
8 the representatives were there.

9 When meetings occurred, was there a
10 practice, from your understanding, that DEA people
11 would want to document it so you know what
12 transpired during the meeting so in the future, you
13 could have a record?

14 MS. ZOLNER: Objection. Form. Objection.
15 Vague. Objection. Vague as to time frame.
16 Objection. Foundation.

17 MR. SHKOLNIK: That's a lot.

18 BY MR. SHKOLNIK:

19 Q. You can still answer it. It was still a
20 good question.

21 A. Yes, that was a practice.

22 Q. And here we have a document that
23 references that there was this meeting on
24 September 12th, and the purpose of the meeting --
25 and I'm going to highlight it here. The purpose of

1 the meeting was to address manufacturing and
2 distribution practices of controlled substances by
3 Actavis.

4 From your experience, was it a practice of
5 DEA to meet with not just distributors, but also
6 meet with manufacturers at times to try to help
7 them understand their obligations and what they
8 should and should not be doing?

9 MS. ZOLNER: Objection. Form.

10 THE WITNESS: DEA investigators in general
11 meeting with manufacturers?

12 BY MR. SHKOLNIK:

13 Q. No. We're talking about headquarters.

14 A. At headquarters?

15 MS. ZOLNER: Objection. Foundation.

16 THE WITNESS: If we're talking about me
17 personally in that time period --

18 BY MR. SHKOLNIK:

19 Q. Not you personally.

20 A. Did DEA meet with manufacturers? I would
21 have to say yes.

22 Q. And here we have an example of it. They
23 had an actual meeting with a manufacturer, and for
24 the purpose -- the purpose of it was to address
25 manufacturing distribution practices of controlled

1 substances by Actavis concentrating on Oxycodone
2 15 milligram and 30 milligrams.

3 Are you -- do you know what Oxycodone 15
4 milligram and 30-milligram tablets are from your
5 experience in the field?

6 MS. ZOLNER: Objection. Form.

7 THE WITNESS: Yes. I know that they're
8 Schedule II controlled substance.

9 BY MR. SHKOLNIK:

10 Q. And those would be drugs -- those are
11 opioids that were -- that would be governed by the
12 Controlled Substances Act, correct?

13 A. Correct.

14 Q. And if we go down into this document, it
15 says that SC -- do you know what SC means?

16 MR. EPPICH: Objection. Foundation.

17 THE WITNESS: Yes.

18 BY MR. SHKOLNIK:

19 Q. Can you tell the Court and jury what SC
20 means.

21 MR. EPPICH: Objection. Foundation.

22 THE WITNESS: Staff coordinator.

23 BY MR. SHKOLNIK:

24 Q. Levin opened the meeting by stating its
25 purpose was both educational and informative.

1 From your experience over the years you
2 were with DEA in Washington, did you find that
3 there were occasions where DEA would want to meet
4 with registrants like manufacturers for the
5 purposes of educating them and giving them
6 information from the DEA?

7 MS. ZOLNER: Objection. Form.

8 THE WITNESS: Yes.

9 BY MR. SHKOLNIK:

10 Q. Was that a good thing?

11 A. Yes.

12 Q. Was that a way that -- from your
13 understanding, that DEA was trying to make sure
14 that the registrants did the right thing?

15 MS. ZOLNER: Objection. Form. Objection.
16 Foundation.

17 MS. BACCHUS: Objection to the form of the
18 question.

19 THE WITNESS: That was one way, yes.

20 BY MR. SHKOLNIK:

21 Q. And it says SC Levin stated he would
22 discuss Actavis's responsibility under the
23 Controlled Substances Act, their suspicious order
24 monitoring system, their procedures concerning due
25 diligence knowing their customers, who their

1 customers sell to, graphs depicting the pharmacies
2 where products were ultimately dispensed. You were
3 asked -- first of all, did I read that correctly?

4 A. Yes.

5 Q. Now, you were asked whether or not there's
6 ever been any writing -- let me withdraw that.

7 You were asked by counsel for Actavis --
8 I'm sorry. Was it Allergan or Actavis -- whether
9 or not there's ever been a writing about
10 manufacturers being told by -- let me rephrase it.

11 You were asked questions by counsel for
12 manufacturers here today as to whether or not there
13 was ever any type of writings to manufacturers that
14 they should know their customer's customers. And I
15 know you weren't shown any documents by counsel,
16 but would you agree with me from your understanding
17 and just generally speaking, not speaking for the
18 DEA, would this be an example of the DEA actually
19 sitting down with a manufacturer and talking to
20 them about knowing your customer's customer?

21 MS. ZOLNER: Objection. Form. Objection.
22 Foundation.

23 MR. EPPICH: Objection. This is also outside
24 the scope. She was not at this meeting. This is
25 going well beyond her personal knowledge.

1 MR. SHKOLNIK: I agree. I would never have
2 brought up the customer's customer issue if I were
3 you.

4 MS. BACCHUS: I'm going to object on the
5 grounds of form.

6 BY MR. SHKOLNIK:

7 Q. Is this an example of DEA -- I'm saying
8 just generally speaking from your understanding,
9 would you look at this and say wow, that is someone
10 at DEA actually telling a manufacturer you've got
11 to know your customer's customer?

12 MS. ZOLNER: Objection. Form. Objection.
13 Foundation.

14 THE WITNESS: Reading this document, it states
15 that it states they should know who their customers
16 sell to.

17 BY MR. SHKOLNIK:

18 Q. And this wasn't a -- from your
19 understanding in 2012, this wasn't a new thing that
20 you need to know your customer and your customer's
21 customer. I mean, that's how you would determine
22 whether or not there's suspicious orders
23 downstream, correct?

24 MS. ZOLNER: Objection. Form. Objection.
25 Foundation. Objection. Compound. Objection.

1 Vague.

2 THE WITNESS: My experience is it's used to
3 determine whether or not a distributor would use it
4 to determine -- or a manufacturer if you should be
5 my customer. It would be part of their approval
6 process.

7 BY MR. SHKOLNIK:

8 Q. From your understanding, is that part of
9 the whole goal of the Controlled Substances Act?
10 You want to make sure that before you start passing
11 the pills, shipping the pills, whether you're a
12 manufacturer, distributor, you want to make sure
13 the person you're distributing to or giving them to
14 downstream should even have those pills or if it's
15 suspicious, correct?

16 MS. ZOLNER: Objection. Form. Objection
17 vague. Objection. Foundation.

18 THE WITNESS: That it is a legitimate business.
19 That's my experience.

20 BY MR. SHKOLNIK:

21 Q. And then he goes on to say Levin stated he
22 would be primarily focusing on distribution of
23 Oxycodone 15 milligrams or 30 milligrams. Turn the
24 page, and I'll ask you a few more questions.

25 Now, if we turn to the second page of

1 Exhibit No. 26, I'm going to go to the top of the
2 second page, and it's the section that starts with
3 Ms. Baron stated that Actavis is just beginning to
4 review their sales through chargeback system.

5 Counsel for the manufacturers asked you
6 about chargeback systems. Generally speaking, what
7 is your knowledge about chargeback systems?

8 MS. BACCHUS: Objection. Asked and answered.

9 BY MR. SHKOLNIK:

10 Q. If you know.

11 MS. BACCHUS: To the extent that you have
12 nonprivileged knowledge, you may answer that
13 question, but the objection stands. It's been
14 asked and answered.

15 THE WITNESS: I don't have any nonprivileged
16 knowledge.

17 BY MR. SHKOLNIK:

18 Q. I'm just going to go above. It says UPS
19 Supply Chain uses their own DEA registration and
20 reports purchases and sales directly to ARCOS.
21 Ms. Baron explained their chargeback system. The
22 system enables Actavis to see who their customers
23 are selling their products to and what they are
24 purchasing.

25 Generally speaking, was that your

1 understanding of what a chargeback system would --
2 the visibility that a chargeback system would give
3 to a manufacturer?

4 MS. ZOLNER: Objection. Form. Objection.
5 Asked and answered. The witness has said she
6 doesn't have any nonprivileged knowledge.

7 MS. BACCHUS: Objection. Asked and answered.

8 BY MR. SHKOLNIK:

9 Q. You can answer.

10 A. This is my understanding as it's written.

11 Q. And as it's written, it's saying the
12 system enables the manufacturer to see who their
13 customers are selling their products to and what
14 they are purchasing.

15 Now, from your general understanding, is
16 that something that should be utilized as part of a
17 suspicious order monitoring system from your
18 understanding?

19 MS. ZOLNER: Objection. Form. Objection.
20 Foundation. Objection. Vague. And objection.
21 Asked and answered.

22 MR. SHKOLNIK: It's called cross.

23 THE WITNESS: It's my expectation that having
24 that information, it would be utilized.

25

1 BY MR. SHKOLNIK:

2 Q. And that, from your understanding, would
3 be any company that has that kind of information.
4 It's information that should be utilized in a
5 suspicious order monitoring order system, correct?

6 MR. NICHOLAS: Object to the form.

7 MS. ZOLNER: Objection.

8 THE WITNESS: It's my expectation that it would
9 be.

10 BY MR. SHKOLNIK:

11 Q. And then it goes on to say she had been
12 visited by UPS Supply Chain and been able to review
13 their suspicious monitoring system. U.S. Supply
14 Chain has a staff which monitors any suspicious
15 orders of controlled substances. Value Centric is
16 a firm who stores sales data for Actavis, which
17 they can review. Recently Ms. Baron has gone to
18 visit large volume customers such as Cardinal,
19 McKesson and AmerisourceBergen. SC Levin mentioned
20 Ms. Baron's significance of knowing your customers.

21 Now, did I read that section correctly?

22 A. Yes.

23 Q. Basically from your general understanding
24 over the 30 years you were with DEA, this is
25 what -- this is an -- this is what you would

1 understand to mean visibility and due diligence.

2 Is that a fair statement?

3 MS. ZOLNER: Objection. Form. Objection.

4 Foundation. Objection. Vague. Objection.

5 Misstates prior testimony.

6 MS. BACCHUS: Objection to the form of the

7 question.

8 THE WITNESS: I agree that this gives

9 visibility, yeah.

10 BY MR. SHKOLNIK:

11 Q. And it says SC Levin stated that the

12 United States, U.S., consumes more legitimately

13 manufactured controlled drugs than any other

14 country. SC Levin mentioned 97 percent of

15 hydrocodone that is manufactured is prescribed and

16 dispensed in the United States.

17 Was that your general understanding back

18 when you were at the DEA?

19 MS. ZOLNER: Objection. Foundation.

20 MS. BACCHUS: Objection. Foundation.

21 BY MR. SHKOLNIK:

22 Q. If you had an understanding.

23 A. Yes, this is a statement that I seen,

24 yeah, and understand from my career.

25 Q. And SC Levin explained the dramatic

1 increase of prescription drug abuse which has
2 increased by 400 percent over the past 10 years.

3 Was that your understanding of what
4 happened over the 10 years prior to 2012 while you
5 were working out in the field for the DEA? Was
6 that your general understanding?

7 MR. NICHOLAS: Objection. Outside the scope of
8 the Touhy letter.

9 MS. BACCHUS: Yeah. I have to agree with that
10 objection. This is getting outside of the scope of
11 her Touhy authorization regarding her
12 communications and what constitutes a suspicious
13 order.

14 MR. SHKOLNIK: Can she answer it?

15 MS. BACCHUS: No.

16 MR. SHKOLNIK: I tried.

17 BY MR. SHKOLNIK:

18 Q. Now, it also goes on to say SC Levin
19 presented a PowerPoint presentation exemplifying
20 the common characteristic issues associated with
21 distribution and manufacturing practices by
22 manufacturers and distributors of controlled
23 substances.

24 First, did I read that correctly?

25 A. Yes.

1 Q. Is this -- from your experience over the
2 years, is this something that DEA, the people you
3 work with at DEA, including yourself, this type of
4 things you did when you worked with the
5 distributors and the manufacturers? You tried to
6 help them understand the common characteristics and
7 issues associated with distribution and
8 manufacturing practices and distribute --
9 distribution of controlled substances. You tried
10 to help them, correct?

11 MS. ZOLNER: Objection. Form. Objection
12 foundation. Objection. Compound. Objection.
13 Vague.

14 MS. BACCHUS: I object to form, and I object on
15 the grounds of vagueness.

16 BY MR. SHKOLNIK:

17 Q. You can answer.

18 A. So yes, in my career, that was -- that's
19 what I did, tried to help registrants remain in
20 compliance with the Controlled Substances Act.

21 Q. And just generally speaking, reading this
22 sentence that SC Levin presented a PowerPoint
23 presenting -- presentation exemplifying the common
24 characteristics and issues associated with the
25 distribution and manufacturing practices by

1 manufacturers and distributors of controlled
2 substances, and SC Levin stressed the importance of
3 manufacturers' due diligence requirements knowing
4 one's customers and detection of suspicious orders.

5 First, did I read that correctly?

6 A. Yes.

7 Q. Reading this, from your general experience
8 being a DEA professional for 30 years, is this the
9 type of practice that DEA would follow in working
10 with the distributors and the manufacturers?

11 MS. ZOLNER: Objection. Form.

12 THE WITNESS: Yes, explaining the requirements.
13 Yes.

14 BY MR. SHKOLNIK:

15 Q. You didn't tell them how to do their job,
16 did you?

17 A. No.

18 MS. ZOLNER: Objection. Form.

19 BY MR. SHKOLNIK:

20 Q. Am I correct?

21 A. No.

22 Q. You didn't tell them how to make their
23 suspicious monitoring system, did you?

24 MS. BACCHUS: Objection.

25 THE WITNESS: We did not tell them how to make

1 their suspicious monitoring system.

2 BY MR. SHKOLNIK:

3 Q. You didn't tell them how to do their due
4 diligence, did you?

5 A. Not how to do it.

6 Q. But you told them they had to do due
7 diligence, correct?

8 A. That is correct.

9 Q. And it was their job to know it and know
10 how to do it, correct?

11 MS. BACCHUS: Objection. Form. You could
12 answer.

13 BY MR. SHKOLNIK:

14 Q. From your understanding.

15 A. We would tell them they had to do it. It
16 was a requirement.

17 Q. And you told them they had to develop a
18 system to determine whether or not they were
19 shipping or not shipping suspicious orders. You
20 told them that was their obligation to do generally
21 speaking, correct?

22 MR. NICHOLAS: Object to the form. Testimony
23 in the form of a question. Go ahead.

24 MR. EPPICH: Object to the time. Vague. No
25 time.

1 THE WITNESS: Yes, we did, or yes, I did talk
2 to registrants about developing their systems for a
3 suspicious order monitoring.

4 BY MR. SHKOLNIK:

5 Q. You didn't go into their offices and say
6 this is what we're going to make and this is how
7 you're going to do it. You said you've got to
8 figure out how to do it, registrant, whether you're
9 a distributor or manufacturer, correct?

10 MR. NICHOLAS: Object to the form.

11 THE WITNESS: That's correct.

12 BY MR. SHKOLNIK:

13 Q. And it was their obligation to follow the
14 law and implement that system, correct?

15 MS. BACCHUS: Objection.

16 THE WITNESS: It was their requirement, yes.

17 BY MR. SHKOLNIK:

18 Q. And when you see here that SC Levin was
19 stressing the importance of manufacturers' due
20 diligence, knowing one's customers and detecting
21 suspicious orders, that type of sentence is not
22 surprising to you because that's what you were
23 doing over the 30 years you were with DEA, wasn't
24 it?

25 MR. NICHOLAS: Object to the form. Lack of

1 foundation. Testimony in the form of a question.

2 MS. BACCHUS: I object to the form of the
3 question.

4 MS. ZOLNER: Objection. Leading.

5 BY MR. SHKOLNIK:

6 Q. You can answer.

7 A. That sentence does not surprise me, no.

8 Q. That's really the right thing to do, from
9 your perspective, as a DEA professional for
10 30 years, correct?

11 MS. ZOLNER: Objection. Form. Objection.
12 Foundation. Objection. Vague.

13 MS. BACCHUS: And she --

14 MR. NICHOLAS: These questions are incredibly
15 leading.

16 MR. SHKOLNIK: I'm crossing the witness. I'm
17 allowed to.

18 MR. NICHOLAS: Is she a hostile witness?

19 MR. SHKOLNIK: You put a witness up.

20 MR. NICHOLAS: Is she a --

21 MR. SHKOLNIK: By the way, there's a ruling on
22 this whole issue from the special master. You
23 weren't there. We're allowed to lead the
24 witnesses.

25 MR. NICHOLAS: Does everyone in the room agree

1 with that?

2 MS. MCNAMARA: No. We were supposed to
3 minimize the leading.

4 MS. ZOLNER: That was my understanding.

5 MR. SHKOLNIK: Go ahead and minimize. You guys
6 did a good job of it. Let's go. I'm not going to
7 waste my time.

8 BY MR. SHKOLNIK:

9 Q. We had a question, I think, that they
10 didn't like. I read that section, and I said from
11 your perspective, what he's describing there, SM
12 Levin, SL Levin, from your perspective as a DEA
13 professional for over 30 years, what he's
14 describing there is the right thing to do from a
15 DEA professional standpoint from your -- from your
16 perspective, correct?

17 MS. ZOLNER: Objection. Form. Objection.
18 Foundation. Objection. Vague.

19 MS. BACCHUS: I'm going to object on the
20 grounds of form. If you have a personal opinion,
21 then you may answer that question, but the
22 objection stands.

23 THE WITNESS: It's my opinion that -- and my
24 experience that DEA -- well, my experience that
25 this is not unusual and that it was our

1 responsibility to work with registrants to
2 understand due diligence.

3 BY MR. SHKOLNIK:

4 Q. There were questions like a couple hours
5 today about -- and you were shown a number of
6 letters and exhibits that talked about the trade
7 organization on behalf of distributors writing to
8 DEA addressing concerns that there was lack of
9 communication. Is that a fair statement of what
10 was presented today to you?

11 A. I agree that was presented today.

12 Q. From your standpoint, during the years you
13 were there, were you seeing a lack of communication
14 with distributors and manufacturers as a general
15 proposition?

16 A. In my field division?

17 MS. MCNAMARA: Objection to form.

18 BY MR. SHKOLNIK:

19 Q. From what you saw.

20 A. My experience is that we engaged a lot,
21 and I'm speaking from the Chicago field division.

22 Q. This would be an example of engaging a
23 manufacturer at the headquarters level just from
24 your understanding, correct?

25 A. Yes.

1 MS. ZOLNER: Objection to form.

2 BY MR. SHKOLNIK:

3 Q. That was 2012 according to this letter,
4 correct?

5 A. Yes.

6 Q. Now, if we just go down, there's a list of
7 items that were specifically reviewed, and one was
8 the knowing your customer. We talked about that
9 already. Am I correct?

10 A. Yes.

11 Q. And then he also -- very interesting he
12 talked to them about recent news articles regarding
13 actions taken against CVS pharmacies, Cardinal and
14 Walgreens.

15 From your perspective, would it be
16 surprising that when you're sitting down with one
17 of the registrants and you're trying to help give
18 them guidance and help that you would want to talk
19 to them about actions that DEA has taken recently
20 and changes that may have been implemented because
21 of those actions? From your perspective, is that
22 something that would not be surprising to do?

23 MS. ZOLNER: Objection. Form. Objection.
24 Foundation. Objection. Vague. And objection.
25 Calls for speculation.

1 MS. BACCHUS: Objection on the grounds of form
2 as well as speculation. You can answer if you
3 know.

4 THE WITNESS: I'm going to -- I'm not clear on
5 the question.

6 BY MR. SHKOLNIK:

7 Q. I'll rephrase the question.

8 From your perspective, if you're meeting
9 with the distributor or manufacturer or registrant
10 and you're trying to give them guidance on what to
11 do or what not to do in terms of their suspicious
12 order monitoring systems, would it be surprising
13 that you would want to discuss with them recent
14 actions DEA took against other registrants so they
15 would have an understanding?

16 MS. ZOLNER: Objection. Form. Objection.
17 Foundation. Objection. Calls for speculation.

18 MS. BACCHUS: Same objection.

19 THE WITNESS: For me, it was not a practice to
20 do it in a one-on-one basis with the registrant.
21 It was more of a practice to do if I were
22 presenting in front of a group.

23 BY MR. SHKOLNIK:

24 Q. And over the years, have you presented to
25 groups on behalf of DEA?

1 A. Yes.

2 Q. And did you talk about prior
3 investigations and resolutions with other
4 registrants to the larger group so they would
5 understand?

6 MS. ZOLNER: Objection. Form. Objection.
7 Vague.

8 THE WITNESS: Cases that have been adjudicated,
9 yes.

10 BY MR. SHKOLNIK:

11 Q. Just generally speaking, if you'd tell the
12 Court and jury why you would want to do that as a
13 DEA professional when you were doing those
14 presentations.

15 MS. ZOLNER: Objection. Form. Objection.
16 Vague.

17 MS. BACCHUS: Objection. Vague.

18 THE WITNESS: I would do that to provide
19 examples to have them understand what the
20 violations were to help them to avoid pitfalls to
21 just have them -- to help to explain DEA's
22 expectation of that registrant.

23 BY MR. SHKOLNIK:

24 Q. And from your perspective, was that
25 something you did over the years, or was there a

1 certain period of time you did that?

2 A. My entire career.

3 Q. And why did you feel that that would be
4 important to do that, to do those kind of
5 presentations to registrants or their trade
6 associations?

7 MS. ZOLNER: Objection. Form.

8 MS. BACCHUS: Objection. Vague.

9 MR. EPPICH: Objection. Misstates testimony.

10 BY MR. SHKOLNIK:

11 Q. You can answer if you can.

12 A. Because those registrants had similar
13 business activities and the same responsibilities
14 under the CSA. So I wanted to provide to them
15 examples of pitfalls and try to help them stay away
16 from those.

17 Q. And you did that because you were a DEA
18 professional in the diversion division over
19 30 years, correct?

20 MS. BACCHUS: Objection. Asked and answered.

21 THE WITNESS: Yes. I felt responsible to do
22 that, part of my responsibilities.

23 BY MR. SHKOLNIK:

24 Q. Now, while you were in the field, it was
25 Chicago. Was that the field office?

1 A. I was in three offices, Washington field
2 division, Detroit field division and Chicago field
3 division.

4 Q. So would Detroit and Chicago, would that
5 be considered the Midwest region of the country?

6 A. Yes.

7 Q. When you were in the Midwest region, did
8 you ever become aware that there was migration of
9 pills from the south up into the -- up into the
10 middle part of the country? Did that become
11 something you became aware of as a DEA
12 investigator?

13 MR. NICHOLAS: Objection. Outside the scope of
14 the Touhy letter.

15 MS. BACCHUS: I would agree with that.

16 MS. MCNAMARA: Objection. Form. Foundation.

17 MS. BACCHUS: I agree it's beyond the scope,
18 and I also agree to the form of the question.

19 BY MR. SHKOLNIK:

20 Q. Let me ask this question. Are you -- have
21 you ever heard of a phrase or a term migration of
22 pills in the area of diversion?

23 MR. NICHOLAS: Objection. This is outside the
24 scope of the Touhy letter.

25 MS. BACCHUS: Yeah, I object on the grounds it

1 is outside the scope of the Touhy request. No, do
2 not answer.

3 BY MR. SHKOLNIK:

4 Q. Go to the next page if we could. Now,
5 when you were having meetings when you were out in
6 the field, you would have discussions with
7 registrants. Did you ever have -- did you ever
8 talk to them about how they may go about
9 determining whether or not there's suspicious
10 activity in some of their customers? Was that a
11 topic you would talk to them about?

12 MS. ZOLNER: Objection. Form. Objection.
13 Foundation. Objection. Vague.

14 THE WITNESS: I recall having discussions about
15 suspicious order monitoring systems at various
16 registrants.

17 BY MR. SHKOLNIK:

18 Q. Now, here we have a section in this
19 letter, and it says SC Levin showed graphs of
20 OxyContin shipped by UPS Supply Chain to
21 distributors and to distributors' customers.

22 That sentence that I just -- first of all,
23 did I read that correctly?

24 A. Yes.

25 Q. That's basically describing knowing your

1 customer's customer in another way, is it not?

2 MS. BACCHUS: Objection.

3 BY MR. SHKOLNIK:

4 Q. Is that your understanding?

5 MS. BACCHUS: Objection to form.

6 BY MR. SHKOLNIK:

7 Q. Personal understanding.

8 MS. ZOLNER: Objection. Form.

9 THE WITNESS: To distributors and to the
10 distributor's customers, yeah. That's the
11 customer's customer.

12 BY MR. SHKOLNIK:

13 Q. And here we have -- it goes on to say that
14 SC Levin advised Ms. Baron that Actavis should send
15 someone from their compliance team to visit
16 pharmacies who were receiving their products in
17 south Florida in order for them to witness long
18 lines at pain clinics, out-of-state licensing
19 plates, questionable clients, security guards in
20 the parking lots and signs stating cash payment
21 only.

22 First, did I read that correctly?

23 A. Yes.

24 Q. Now, just your understanding, personal
25 understanding, not DEA's, what's written here when

1 someone goes to look at a pharmacy, when you're
2 telling a registrant to go look at a pharmacy and
3 look for things such as long lines at pain clinics,
4 out-of-state license plate, questionable clients,
5 security guards, cash payment, from your personal
6 perspective, what would that be? What is the
7 significance of those items?

8 MS. ZOLNER: Objection. Form. Objection.
9 Compound. Objection. Vague.

10 MS. BACCHUS: Objection on the grounds that
11 it's vague.

12 THE WITNESS: The significance is to help them
13 determine if they have a customer that's running a
14 legitimate business or if they want to move forward
15 with continuing having them as their customer.

16 MS. MCNAMARA: Excuse me. Can we go off the
17 record for a second.

18 THE VIDEOGRAPHER: We're off the record at
19 6:04 p.m.

20 (Whereupon, a short break was
21 taken.)

22 THE VIDEOGRAPHER: We're back on the record at
23 6:34 p.m.

24 BY MR. SHKOLNIK:

25 Q. Ms. Ashley, I'm just going to continue

1 where we left off. If we go back to the letter,
2 the next line is SC Levin, Chief Boockholdt. Do
3 you know who Chief Boockholdt was? Did you
4 ever meet --

5 A. Oh, yeah, Barbara Boockholdt.

6 Q. Who was that?

7 A. She was the section chief of the -- it was
8 the regulatory section headquarters in D.C.

9 Q. So based on this from your understanding
10 of what we're seeing here is there wasn't just SC
11 Levin, but there was actually another -- there was
12 different portions of the different people from the
13 DEA at this meeting with this manufacturer?

14 A. Yes.

15 MR. DAVISON: Object to form. Foundation.
16 Lacks foundation.

17 BY MR. SHKOLNIK:

18 Q. SC Levin and Chief Boockholdt stressed to
19 Ms. Baron and other Actavis representatives to get
20 to know their customers, visit distribution sites,
21 visit customers of those distributors, check on
22 customer suspicious ordering monitoring, review due
23 diligence files and obtain printouts of pharmacies
24 or practitioners who were receiving Actavis
25 products.

1 First, did I read that correctly?

2 A. Yes.

3 Q. Now, from your experience as a 30-year
4 veteran in the DEA, an interaction like we're
5 reading here where a distributor -- I'm sorry, a
6 manufacturer is being told, you know, that they
7 should know their customers, visit distribution
8 sites, visit customers of distributors, check on
9 customers' suspicious ordering systems, review due
10 diligence files, obtain printouts of pharmacies or
11 practitioners who are receiving Actavis or
12 manufacturer products.

13 From your perspective, just generally
14 speaking, not speaking for the DEA, would you
15 consider that to be the type of working with
16 registrants to help them understand what their job
17 is, what their obligations are under the Controlled
18 Substances Act?

19 MS. ZOLNER: Objection to form.

20 THE WITNESS: This would be a normal part of a
21 conversation for me in my career --

22 BY MR. SHKOLNIK:

23 Q. I mean --

24 A. -- with a registrant.

25 Q. I think you hit what my next question was

1 going to be.

2 Is this surprising that somebody from DEA
3 was having a conversation and going through such
4 details with a registrant from your perspective?

5 MS. BACCHUS: Objection.

6 MR. DAVISON: Object to form.

7 THE WITNESS: This statement does not surprise
8 me.

9 BY MR. SHKOLNIK:

10 Q. From your perspective, is that what you
11 believed as a DEA -- member of the DEA in the
12 diversion division that that was what you should be
13 doing when you're working with registrants,
14 manufacturers or distributors?

15 A. I felt it was my responsibility, yes.

16 Q. And you took that responsibility very
17 seriously over your 30 years with the Drug
18 Enforcement Agency, correct?

19 A. I took that responsibility seriously, yes.

20 Q. And just so I understand from your
21 perspective, if there's any suggestion that
22 professionals like yourself were not trying to do
23 your best to prevent diversion, what is your
24 position on that? Do you believe the DEA was not
25 trying to do their best over the years you were

1 there?

2 MR. MAHADY: Object to form.

3 MR. DAVISON: Objection to form.

4 MS. BACCHUS: Objection to form.

5 THE WITNESS: I believe the mission of DEA was
6 to ensure compliance with the Controlled Substances
7 Act, and I believe that's what the diversion
8 control division worked toward.

9 BY MR. SHKOLNIK:

10 Q. And yourself, is that what you tried do as
11 best as you could over the 30 years you were there?

12 A. I did, yes, in my 30-year career.

13 Q. And while you were doing your job over
14 that 30-year career, you actually went up through
15 the ranks of DEA, did you not?

16 A. That's correct, yes.

17 Q. I mean, the fact that you were at the
18 field and then asked to go to Washington and then
19 go up into headquarters, does that happen with
20 everybody in DEA? Is that everybody's progression?

21 A. That's not everyone's progression,
22 correct.

23 Q. And in terms of the -- and I'm not trying
24 to say it inappropriately, but in terms of the
25 pecking order, you went up pretty high up into DEA,

1 didn't you?

2 A. That's correct.

3 MR. DAVISON: Objection to form.

4 BY MR. SHKOLNIK:

5 Q. And when you retired -- let me say when
6 you were in headquarters and you held -- I don't
7 want to misstate the position. It was assistant
8 director of diversion?

9 A. It was -- my last position was acting
10 assistant administrator.

11 Q. Where is that in terms of DEA in terms of
12 hierarchy at DEA?

13 A. In DEA -- excuse me. In DEA, there's the
14 administrator. Then there's the deputy
15 administrator, and then there were seven
16 individuals at my level, acting assistant
17 administrators, and we controlled -- we managed
18 seven separate divisions.

19 Q. And how many people were under your
20 supervision when you reached the highest level at
21 DEA?

22 A. Under my management, it was about 1,500
23 globally.

24 Q. Now, I'm going to go on a little bit
25 further. Ms. Baron stated Actavis only recently

1 begun looking at the pharmacies that purchased
2 their products and wants to be involved in working
3 to resolve this problem. SC Levin stated that if
4 their customers refused to provide them with sales
5 information, Actavis should consider cutting them
6 off.

7 Did I read that correctly?

8 A. Yes.

9 Q. Now, just from your perspective --

10 MR. SHKOLNIK: And I'm asking Ms. Ashley's
11 position on this, not DEA.

12 BY MR. SHKOLNIK:

13 Q. -- is this the type of recommendation that
14 you would suggest to a registrant when you were
15 having a meeting with them over the years you were
16 there?

17 MS. ZOLNER: Objection. Form. Objection.
18 Foundation.

19 THE WITNESS: I may not have used that
20 language, something similar maybe.

21 BY MR. SHKOLNIK:

22 Q. If you have a customer, if a registrant
23 has a customer who doesn't want to be forthcoming
24 with information, from your perspective, is that of
25 any significance?

1 MS. ZOLNER: Objection. Form.

2 MR. EPPICH: Objection. Form.

3 THE WITNESS: It's significant if the customer
4 is not being forthcoming with all their business
5 practices.

6 BY MR. SHKOLNIK:

7 Q. And why would that be?

8 A. Because you need that information to
9 determine if it's legitimate.

10 Q. I'm going to turn to Page 4. Now, I'm
11 going to turn to the middle of that first paragraph
12 on Page 4. SC Levin asked representatives from
13 Actavis to take a serious look at their quota
14 request, review their suspicious order monitoring
15 system, visit their customers to review their
16 customers -- I'm sorry. Review their -- I'm sorry.
17 Visit their customers to review their suspicious
18 order monitoring system as well as their due
19 diligence files and ask to see customers' top
20 customers for Actavis products and contact their
21 local DEA office with any questions.

22 Did I read that correctly?

23 A. Yes.

24 Q. Did I say that correctly after I stumbled
25 twice?

1 A. Yes.

2 Q. And now, in reading that, from your
3 perspective, and this is your personal perspective,
4 Ms. Ashley, is that consistent with the practices
5 that you saw at DEA while you were there working?

6 MS. ZOLNER: Objection. Foundation.

7 THE WITNESS: This is consistent with
8 statements I would have made.

9 BY MR. SHKOLNIK:

10 Q. And I'm going to read the next area. SC
11 Levin mentioned that salespeople -- I'm sorry. I
12 skipped.

13 Ms. Baron stated that their sales force
14 has been informed to keep management abreast of
15 what is going on in the field. SC Levin mentioned
16 that salespeople are generally on commission and
17 may not be subjective when it comes to their
18 accounts' purchasing suspicious or unusual orders
19 of controlled substances.

20 First, did I read that correctly?

21 A. Yes.

22 Q. From your experience at DEA over the
23 30 years, are statements such as salespeople are
24 generally on commission and may not be objective
25 when it comes to their accounts' purchasing

1 suspicious or unusual orders of controlled
2 substances, is that the type of discussions that
3 would sometimes occur at DEA when talking to
4 registrants?

5 MR. MAHADY: Objection. Form. Objection.
6 Foundation.

7 MS. BACCHUS: Objection. Form and foundation,
8 if you know.

9 THE WITNESS: I don't know.

10 BY MR. SHKOLNIK:

11 Q. Let me go down to the second to last
12 paragraph. SC Levin explained that the purpose of
13 this meeting was to inform, educate and provide
14 pertinent ARCOS data, discuss national trends and
15 discuss the pain management epidemic in Florida
16 involving Oxycodone. DEA is seeking to partner
17 with drug distributors and manufacturers in
18 resolving this problem.

19 First, did I read that accurately?

20 A. Yes.

21 Q. From your perspective back over the years
22 that you were at DEA, did you feel that DEA wanted
23 to partner with the registrant distributors and
24 manufacturers to try to resolve the epidemic as it
25 was developing?

1 MR. MAHADY: Object to form.

2 MR. DAVISON: Object to form.

3 THE WITNESS: I would say work with them, yes.

4 BY MR. SHKOLNIK:

5 Q. And SC Levin asked if there were any
6 questions. There were none, and you -- first of
7 all, did I read that correctly?

8 A. Yes.

9 Q. From your perspective at DEA over the
10 years, when you had your meetings with registrants,
11 whether it's a manufacturer, distributor or a
12 pharmacy or a big box chain pharmacy, whatever it
13 is, would you also say to them, you know, do you
14 have any questions for us, and did you try to
15 answer the questions when they were posed?

16 MS. ZOLNER: Objection. Form.

17 THE WITNESS: Yes.

18 BY MR. SHKOLNIK:

19 Q. Why would you do that?

20 A. I wanted to make sure they had an
21 understanding of what we spoke about, if they had
22 any follow-up questions. I wanted to make sure we
23 were clear.

24 Q. And you were asked a lot of questions
25 earlier today about whether or not, from your

1 understanding, the DEA tried to help registrants
2 understand what they can do in terms of due
3 diligence, and you were specifically asked about
4 whether or not the reg itself outlined what was
5 supposed to be done.

6 Do you recall those questions?

7 A. I do.

8 Q. Now, I'm correct in stating that the
9 statute and reg does not tell them how to do their
10 job, the registrants, correct?

11 A. That's correct.

12 Q. It is the law, and it is the regulations
13 that they must follow. Fair statement?

14 MR. MAHADY: Objection. Form.

15 THE WITNESS: That's a fair statement.

16 BY MR. SHKOLNIK:

17 Q. That was your understanding over all the
18 years you were there because they were promulgated
19 long before you started?

20 A. That's correct.

21 Q. And they were still in place to the day
22 you left, correct?

23 A. That's correct.

24 Q. I mean, there's no question the industry
25 wanted DEA to change the regs. Fair statement.

1 MR. MAHADY: Objection to form.

2 THE WITNESS: That's my experience, yes.

3 BY MR. SHKOLNIK:

4 Q. And over the last few years you were
5 there, their trade organization spent a lot of time
6 trying to work with DEA to change the regs,
7 correct?

8 MS. ZOLNER: Objection. Form. Objection.
9 Vague.

10 MR. EPPICH: Objection. Foundation.

11 MS. BACCHUS: Objection. Form.

12 MR. SHKOLNIK: Foundation? You guys used the
13 documents.

14 THE WITNESS: There was communication, correct.

15 BY MR. SHKOLNIK:

16 Q. And irrespective of the agency, from your
17 perspective, the agency was considering changes,
18 working on drafts, suggesting a timeline to
19 promulgate them or not. The registrants over that
20 period of time, all this period of time, and I'm
21 saying from when that first letter in 2010 to the
22 last communication when you left in 2018, those
23 registrants still had the same obligations to
24 comply with the CSA and the existing regulations.
25 Fair statement?

1 MR. MAHADY: Objection. Form.

2 THE WITNESS: Yes, they had the obligation to
3 comply with the existing regulation. Yes.

4 BY MR. SHKOLNIK:

5 Q. Even if they wanted to change them, until
6 they were changed, the law is the law, and the
7 regulation is the regulation, correct?

8 MR. MAHADY: Objection. Form.

9 THE WITNESS: Yes. The law was the law in
10 place, yes.

11 BY MR. SHKOLNIK:

12 Q. And correct me if I'm wrong. The
13 obligation -- I'm sorry. The decision to ship an
14 order, a suspicious order or not suspicious order,
15 that wasn't the DEA making that decision at any
16 time under the CSA or the regulation, correct?

17 A. That is correct.

18 Q. From your perspective, whose obligation
19 was it to ship or not ship?

20 MS. BACCHUS: Objection. Asked and answered.

21 MR. MAHADY: Objection. Form.

22 BY MR. SHKOLNIK:

23 Q. You can answer.

24 A. It was the seller.

25 Q. I'm not going to go through all this, but

1 also attached to this Exhibit 26 at the back of the
2 presentation was a three-page additional document
3 entitled suggested questions a distributorship
4 should ask prior to delivering controlled
5 substances. Did you have a chance to turn to it?

6 A. Yes.

7 Q. That was the heading. Am I correct? I
8 read that right?

9 A. Yes.

10 Q. And if I'm not mistaken, this is -- the
11 DEA was actually giving this manufacturer on
12 this -- at this meeting a set of questions that
13 they could possibly ask in order to do their job,
14 their due diligence job, correct?

15 MR. KOBRIN: Objection. Outside the scope.

16 MS. BACCHUS: Objection. Foundation.

17 THE WITNESS: The question again?

18 BY MR. SHKOLNIK:

19 Q. The question is from what we can see in
20 this document, DEA was actually giving a three-page
21 suggested list of questions to help a distributor
22 or a manufacturer perform its due diligence. Is
23 that a fair statement?

24 MS. BACCHUS: Same objection.

25 MR. KOBRIN: Same objection.

1 THE WITNESS: Yes. Based on the title, I would
2 say yes.

3 BY MR. SHKOLNIK:

4 Q. There were suggestions here today that DEA
5 didn't do anything and didn't give them any
6 guidance and didn't help these distributors and
7 just didn't answer -- basically didn't pick up the
8 phone and talk to them. Is that a fair statement,
9 from your perspective, for the 30 years you were at
10 DEA?

11 MR. MAHADY: Objection to form.

12 MS. MCNAMARA: Objection to form.

13 MS. ZOLNER: Objection. Vague.

14 THE WITNESS: My experience personally, no,
15 that was not my experience.

16 BY MR. SHKOLNIK:

17 Q. They showed you three letters, three
18 letters from pharmacies across the United States
19 today. Withdraw that.

20 The list of questions is not intended to
21 be all-inclusive, nor should it be interpreted that
22 every situation or registrant activity is covered.
23 This questionnaire is provided to assist the
24 distributor to formulate a better understanding of
25 who their customers are and whether or not they

1 should sell to them controlled substances.

2 Did I read that correctly?

3 A. Yes.

4 Q. Was that your understanding of what the
5 obligations were of each of these registrants that
6 are named as defendants in this case --

7 MR. NICHOLAS: Object to --

8 MS. BACCHUS: Objection to form.

9 BY MR. SHKOLNIK:

10 Q. -- from your personal perspective?

11 A. From my personal experience, yes, it was
12 the registrant's discretion and responsibility.

13 Q. It is incumbent upon you, the
14 distributors, to ensure that sales of your
15 customers are for legitimate purposes.

16 Did I read that correctly?

17 A. Yes.

18 Q. Was that your understanding of the
19 obligations for all the years you were there at
20 DEA?

21 A. Yes, this is my understanding.

22 Q. It is further incumbent upon you to
23 identify illicit or suspicious activities which may
24 result in the diversion of controlled substances.

25 Did I read that correctly?

1 A. Yes.

2 MR. NICHOLAS: Object to the form.

3 BY MR. SHKOLNIK:

4 Q. Was that your understanding as well?

5 MR. NICHOLAS: Object to the form.

6 THE WITNESS: My understanding was to have
7 systems in place to detect suspicious activities.

8 BY MR. SHKOLNIK:

9 Q. And that was to prevent diversion,
10 correct?

11 A. To prevent diversion, correct.

12 Q. And so now, I'm not going to go through
13 all the questions here, but correct me if I'm
14 wrong. There's a list of questions that you
15 possibly would want to do if it was a pharmacy,
16 correct, if you were doing due diligence on a
17 pharmacy?

18 MS. ZOLNER: Objection. Form.

19 THE WITNESS: Yes, that's what it states here.
20 Yes.

21 BY MR. SHKOLNIK:

22 Q. And there's another one if you're speaking
23 to practitioners, doctors, I guess, correct?

24 A. Yes, that's what it states. Yes.

25 Q. And once again, the document that was

1 shown to this manufacturer on that day,
2 September 12, 2012 said if you have any additional
3 questions, concerns or issues beyond what has been
4 presented, it is strongly recommended you contact
5 your local DEA office.

6 Was that your understanding -- first of
7 all, did I read that correctly?

8 A. Yes.

9 Q. Was that your understanding of the
10 practices at DEA during the 30 years you were
11 there?

12 MS. BACCHUS: Objection. Foundation.

13 MS. MCNAMARA: Objection. Form.

14 MS. BACCHUS: Form and vague.

15 THE WITNESS: That was my practice, yes.

16 BY MR. SHKOLNIK:

17 Q. And now -- the Controlled Substances Act,
18 would I be correct in stating that it was enacted
19 to protect the public from the danger of diversion
20 related to opioids or any controlled substance?

21 MR. NICHOLAS: Object to the form.

22 MS. MCNAMARA: Object to the form. Foundation.

23 MS. ZOLNER: Scope.

24 BY MR. SHKOLNIK:

25 Q. Was that your understanding?

1 A. Repeat that.

2 Q. I'll try it again.

3 Was it your understanding that the
4 Controlled Substances Act was meant to protect the
5 public from potential diversion of controlled
6 substances?

7 MR. NICHOLAS: Objection. I believe this is
8 outside the scope of the Touhy letter.

9 MS. BACCHUS: I agree. Objection. No, you
10 will not answer. It's outside the scope of the
11 Touhy letter.

12 BY MR. SHKOLNIK:

13 Q. You were asked questions about the
14 government's resources -- you were asked questions
15 about government resources and how many employees
16 were there and how many field officers and whether
17 or not you were properly staffed. I mean, you were
18 asked those questions earlier, were you not?

19 A. Yes.

20 Q. I think the suggestion was that maybe you
21 didn't have -- DEA didn't have enough people to do
22 their job. Was that your understanding? DEA
23 couldn't do their job?

24 MS. ZOLNER: Objection.

25 MS. BACCHUS: Objection.

1 MS. ZOLNER: These were all questions that I
2 was told I could not explore.

3 MR. SHKOLNIK: I thought you did ask.

4 MS. ZOLNER: No.

5 MS. BACCHUS: She asked them, and I told her
6 they were outside the scope.

7 MR. SHKOLNIK: I'm glad. I thought I wrote
8 down answers. Maybe I made up the answers, and
9 they were good. Believe me.

10 BY MR. SHKOLNIK:

11 Q. I'm just going to -- I'm just going to ask
12 a couple follow-up, and I'll be done.

13 From your perspective, what is diversion
14 from your understanding?

15 A. Diversion is when -- from an
16 investigator's perspective is when the controlled
17 substances goes to a place where it's not intended.

18 Q. Would excessive -- from your perspective,
19 would excessive amount of pills going out into the
20 communities or being distributed as a result of
21 diversion, what is the -- what does that cause?
22 What is the significance of that?

23 MR. NICHOLAS: Objection. Outside the scope of
24 the Touhy letter.

25

1 BY MR. SHKOLNIK:

2 Q. From your perspective, why were you doing
3 your job to try to prevent diversion? What was --
4 I'm just trying to get your perspective on it.

5 A. To prevent diversion, it's to protect the
6 public to prevent misuse, abuse of controlled
7 substances and to make sure that the controlled
8 substances go to the right place, the place they
9 were intended to go.

10 Q. If an excessive amount of pills that go
11 out into the marketplace that are to the point
12 where they're going to where they're not intended
13 to go, what is the significance of that from your
14 perspective?

15 MR. NICHOLAS: Objection. Outside the scope of
16 the Touhy letter.

17 MS. BACCHUS: I agree. Objection. Outside the
18 scope. You're not to answer that question.

19 BY MR. SHKOLNIK:

20 Q. When you first started going this morning,
21 counsel asked you whether or not you were retained
22 as an expert for anybody in this case, and I think
23 your answer was yes, and it was Purdue. Am I
24 correct?

25 A. Yes.

1 Q. When did that occur?

2 MS. MACKAY: Objection. This is -- it's on the
3 record that the witness has been retained by
4 Purdue, but she is a nontestifying --

5 MR. SHKOLNIK: So what?

6 MS. MACKAY: -- expert consultant under
7 Rule 26. This type of questioning is not permitted
8 and is privileged.

9 MR. SHKOLNIK: Well, do you --

10 MS. MACKAY: I'm not finished.

11 MR. SHKOLNIK: I'm sorry.

12 MS. MACKAY: This is Purdue's privilege that we
13 are asserting, and I would instruct the witness not
14 to answer.

15 MR. SHKOLNIK: Okay. We can get Special Master
16 Cohen if you'd like, but for a DEA officer, Kyle
17 Wright, the exact same issue came up, and he
18 allowed us to ask when was the person retained, who
19 retained you, did anyone else try to retain you,
20 when they did that. I'm not going into specifics,
21 and we're allowed to do that, and there's already
22 an order in place. If you want to get him back on,
23 I'm sure he would like to disrupt his dinner.

24 MS. MACKAY: I've read the Wright transcript.
25 I'm aware that some questions were permitted. Some

1 were not permitted, but we're not going to waive
2 the privilege or any objection, so we stand by it.
3 I would offer maybe one suggestion procedurally so
4 we only have to call one time. If maybe you would
5 want to run through all your questions, I could
6 just object, and then we could run them all by him.

7 MR. SHKOLNIK: Okay. Sure.

8 BY MR. SHKOLNIK:

9 Q. When were you retained by Purdue?

10 MS. MACKAY: So again, for the record, I object
11 that it's privileged, and I instruct the witness
12 not to answer.

13 BY MR. SHKOLNIK:

14 Q. For how long have you been a retained
15 expert for Purdue?

16 MS. MACKAY: I object as to privilege, and I
17 instruct the witness not to answer.

18 BY MR. SHKOLNIK:

19 Q. Have you had any meetings with anyone at
20 Purdue other than with their outside counsel?

21 MS. MACKAY: Again, I object. It's privileged,
22 and I instruct the witness not to answer.

23 BY MR. SHKOLNIK:

24 Q. Have you been retained by any other
25 manufacturers or distributors to be an expert in

1 any capacity?

2 MS. MACKAY: That would not be my objection to
3 assert, but I --

4 MR. SHKOLNIK: You don't have an objection to
5 that?

6 MS. MACKAY: I do have an objection to that
7 question, but it's not my privilege to assert. I
8 would suggest that her counsel, perhaps, advise her
9 not to answer that question.

10 MS. BACCHUS: I'm not going to advise you not
11 to answer. What I am going to say is I that object
12 on the grounds that that question was asked and
13 answered before.

14 MR. SHKOLNIK: I didn't hear it earlier. I'm
15 sorry.

16 BY MR. SHKOLNIK:

17 Q. Were you -- have you been retained by any
18 other entity, whether it's a manufacturer or
19 distributor, with respect to giving expert opinions
20 first in this litigation?

21 A. No.

22 MS. MACKAY: I would renew my objection. I
23 assume you're asking about other than Purdue?

24 MR. SHKOLNIK: Yeah. That's why I said other.

25 THE WITNESS: In this litigation, no.

1 BY MR. SHKOLNIK:

2 Q. Have you been retained by any
3 manufacturers or distributors as an expert with
4 respect to the Controlled Substances Act other than
5 Purdue and not in this litigation?

6 A. No.

7 Q. Have you been consulted by any other
8 manufacturers or distributors to determine whether
9 or not you would be an expert for them on any of
10 the issues relating to Controlled Substances Act,
11 diversion or the type of claims being made here?

12 MS. MACKAY: Other than Purdue?

13 MR. SHKOLNIK: Other than Purdue.

14 MS. BACCHUS: Objection to the form of the
15 question. Did you mean consulted or contacted?
16 I'm sorry.

17 BY MR. SHKOLNIK:

18 Q. Consulted or contacted, either/or.

19 A. Contacted, yes.

20 Q. And could you tell us the names of the
21 people who contacted you to be an expert?

22 A. I won't remember them all.

23 Q. That's all right.

24 A. I can tell you the ones I do remember.

25 Q. Sure.

1 A. I remember Reed Smith. I'm drawing a
2 blank on the names. I can say there have been
3 several. I don't remember all the firms.

4 Q. Are you considering retention by those
5 other manufacturers or distributors in this
6 litigation?

7 A. No.

8 Q. You've rejected the overtures; fair
9 statement?

10 A. Yes, fair statement.

11 Q. Is that because you're under retainer for
12 Purdue?

13 MS. MACKAY: Objection. To the extent that
14 calls for a privileged response, I would instruct
15 the witness not to answer.

16 BY MR. SHKOLNIK:

17 Q. You can answer that. She can't instruct
18 you not to answer it.

19 MS. MACKAY: I can instruct to the extent that
20 it's going to reveal privileged information. That
21 is a privilege that belongs to Purdue, and I would
22 instruct the witness not to answer.

23 MR. SHKOLNIK: You can't.

24 MS. MACKAY: Maybe you just want to rephrase
25 your question.

1 MR. SHKOLNIK: No. My question was very good.

2 MS. MACKAY: Well, I beg to differ.

3 BY MR. SHKOLNIK:

4 Q. Did you reject the overtures to be hired
5 as an expert by other manufacturers, I'll start
6 with other manufacturers, because you're under
7 retainer with Purdue?

8 MS. MACKAY: I would just renew my same
9 objections and instruct the witness not to answer
10 that question to the extent it would reveal the
11 privilege.

12 BY MR. SHKOLNIK:

13 Q. You're allowed to answer that.

14 MS. BACCHUS: The government takes no position.
15 That's not our fight.

16 THE WITNESS: Okay. Repeat the question one
17 more time. Did I --

18 BY MR. SHKOLNIK:

19 Q. I can rephrase it.

20 Why did you reject retention by other
21 manufacturers in this case?

22 A. Because I'm busy with other clients.

23 Q. That was easy.

24 MR. SHKOLNIK: Thank for all your time, and I
25 have no further questions.

1 MR. NICHOLAS: We need 10 minutes to decide
2 what, if any, other questions we have.

3 THE VIDEOGRAPHER: We are off the record at
4 7:02 p.m.

5 (Whereupon, a short break was
6 taken.)

7 THE VIDEOGRAPHER: We are back on the record at
8 7:16 p.m.

9 MR. SCHUTTE: Good evening, Ms. Ashley. I know
10 it's been a long day, so I'll be quick.

11 FURTHER EXAMINATION

12 BY MR. SCHUTTE:

13 Q. My first question is on Exhibit 26, which
14 is a document that Mr. Shkolnik asked you a series
15 of questions about. It's the memo about the
16 Actavis meeting.

17 My first question is just to confirm for
18 the record you were not in attendance at the
19 meeting that's described in this memo, correct?

20 A. That's correct.

21 Q. And isn't it also correct that you had not
22 seen this document before today?

23 A. I don't recall ever seeing it, correct.

24 Q. Thank you. You can put that aside.

25 My second question for you, ma'am, is that

1 Mr. Shkolnik asked you questions about whether you
2 were contacted by any of the defendants, other
3 registrants about being retained. I'll ask the
4 same question. Were you contacted by any city or
5 state, county government or lawyer for a government
6 to represent or to consult with them with respect
7 to this litigation?

8 A. Not directly, no.

9 Q. Were you contacted indirectly?

10 A. Indirectly, yes.

11 Q. Can you tell us about that?

12 A. It was a colleague that contacted me, a
13 former colleague contacted me and wanted to put
14 together a conversation between myself and one of
15 the plaintiff attorneys to see if I could be a
16 consultant.

17 Q. And who was that colleague?

18 A. Now I'm drawing a blank on his name. Oh,
19 God. He's a retired DEA agent, and now I can't
20 think of his name. I'm drawing a blank, but I do
21 know him. I just can't think of his name right
22 now.

23 Q. And what was your response?

24 A. I did not.

25 Q. What was the reason you did not?

1 MS. MACKAY: I would just again object to the
2 extent this answer calls for privileged information
3 and instruct the witness not to answer to that
4 extent.

5 MR. SCHUTTE: I'll withdraw the question.

6 BY MR. SCHUTTE:

7 Q. My last line of questions is regarding
8 Mr. Shkolnik's questions to you about whether
9 during your career at DEA you encountered
10 registrants that were not complying with the
11 requirements of the CSA and the implementing regs.
12 Do you recall that?

13 A. Yes.

14 Q. In your, frankly, remarkable career of
15 rising from a secretary all the way up to an
16 executive at DEA, isn't it the case, Ms. Ashley,
17 that the vast majority of registrants with whom you
18 dealt were trying to comply with the CSA and the
19 implementing regs?

20 MS. BACCHUS: Objection. Asked and answered.
21 You can answer.

22 THE WITNESS: I agree with that, yes.

23 BY MR. SCHUTTE:

24 Q. And isn't it correct that when the
25 registrants were contacting you about asking for

1 more guidance, they were asking for guidance to
2 help them comply with the regulation; isn't that
3 correct?

4 MS. BACCHUS: Objection. Asked and answered.
5 You can answer.

6 THE WITNESS: I agree with that.

7 MR. SCHUTTE: That's all we have. Thank you
8 very much for your time.

9 MS. BACCHUS: Before we go off the record, I
10 just need to make a clarification that the
11 government does not represent Ms. Ashley in her
12 personal capacity. We are here to protect the
13 government's information. I think there was some
14 reference about being her personal counsel. Thank
15 you.

16 MR. SCHUTTE: Thank you for your time and
17 patience.

18 THE VIDEOGRAPHER: We are off the record. We
19 are off the record at 7:20 p.m.

20 MS. BACCHUS: She will not waive signature.
21 She wants to read it.

22 (FURTHER DEPONENT SAITH NAUGHT.)
23
24
25

1 STATE OF ILLINOIS)

2) SS:

3 COUNTY OF C O O K)

4 I, GINA M. LUORDO, a notary public within
5 and for the County of Cook County and State of
6 Illinois, do hereby certify that heretofore,
7 to-wit, on March 15, 2019, personally appeared
8 before me, at 10 South Wacker Drive, Suite 4000,
9 Chicago, Illinois, DEMETRA ASHLEY, in a cause now
10 pending and undetermined in the United States
11 District Court of Cook County, Northeastern
12 District of Ohio, In Re National Prescription
13 Opiate Litigation.

14 I further certify that the said DEMETRA
15 ASHLEY was first duly sworn to testify the truth,
16 the whole truth and nothing but the truth in the
17 cause aforesaid; that the testimony then given by
18 said witness was reported stenographically by me in
19 the presence of the said witness, and afterwards
20 reduced to typewriting by Computer-Aided
21 Transcription, and the foregoing is a true and
22 correct transcript of the testimony so given by
23 said witness as aforesaid.

24 I further certify that the signature to
25 the foregoing deposition was not waived by counsel

1 for the respective parties.

2 I further certify that the taking of this
3 deposition was pursuant to notice and that there
4 were present at the deposition the attorneys
5 hereinbefore mentioned.

6 I further certify that I am not counsel
7 for nor in any way related to the parties to this
8 suit, nor am I in any way interested in the outcome
9 thereof.

10 IN TESTIMONY WHEREOF: I have hereunto set
11 my hand and affixed my notarial seal this 20th day
12 of March, 2019.

13
14
15
16 

17
18 NOTARY PUBLIC, COOK COUNTY, ILLINOIS
19 LIC. NO. 084-004143
20
21
22
23
24
25

Veritext Legal Solutions
1100 Superior Ave
Suite 1820
Cleveland, Ohio 44114
Phone: 216-523-1313

March 20, 2019

To: RENEE A. BACCHUS

Case Name: In Re: National Prescription Opiate Litigation v.

Veritext Reference Number: 3251436

Witness: Demetra Ashley Deposition Date: 3/15/2019

Dear Sir/Madam:

Enclosed please find a deposition transcript. Please have the witness review the transcript and note any changes or corrections on the included errata sheet, indicating the page, line number, change, and the reason for the change. Have the witness' signature notarized and forward the completed page(s) back to us at the Production address shown above, or email to production-midwest@veritext.com.

If the errata is not returned within thirty days of your receipt of this letter, the reading and signing will be deemed waived.

Sincerely,
Production Department

NO NOTARY REQUIRED IN CA

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DEPOSITION REVIEW
CERTIFICATION OF WITNESS

ASSIGNMENT REFERENCE NO: 3251436
CASE NAME: In Re: National Prescription Opiate Litigation v.
DATE OF DEPOSITION: 3/15/2019
WITNESS' NAME: Demetra Ashley

In accordance with the Rules of Civil
Procedure, I have read the entire transcript of
my testimony or it has been read to me.

I have made no changes to the testimony
as transcribed by the court reporter.

Date Demetra Ashley
Sworn to and subscribed before me, a
Notary Public in and for the State and County,
the referenced witness did personally appear
and acknowledge that:

They have read the transcript;
They signed the foregoing Sworn
Statement; and
Their execution of this Statement is of
their free act and deed.

I have affixed my name and official seal
this _____ day of _____, 20____.

Notary Public

Commission Expiration Date

DEPOSITION REVIEW
CERTIFICATION OF WITNESS

ASSIGNMENT REFERENCE NO: 3251436

CASE NAME: In Re: National Prescription Opiate Litigation v.

DATE OF DEPOSITION: 3/15/2019

WITNESS' NAME: Demetra Ashley

In accordance with the Rules of Civil Procedure, I have read the entire transcript of my testimony or it has been read to me.

I have listed my changes on the attached Errata Sheet, listing page and line numbers as well as the reason(s) for the change(s).

I request that these changes be entered as part of the record of my testimony.

I have executed the Errata Sheet, as well as this Certificate, and request and authorize that both be appended to the transcript of my testimony and be incorporated therein.

Date

Demetra Ashley

Sworn to and subscribed before me, a Notary Public in and for the State and County, the referenced witness did personally appear and acknowledge that:

They have read the transcript;
They have listed all of their corrections in the appended Errata Sheet;
They signed the foregoing Sworn Statement; and
Their execution of this Statement is of their free act and deed.

I have affixed my name and official seal
this _____ day of _____, 20____.

Notary Public

Commission Expiration Date

ERRATA SHEET

VERITEXT LEGAL SOLUTIONS MIDWEST

ASSIGNMENT NO: 3/15/2019

PAGE/LINE (S)	CHANGE	/REASON
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Date _____ Demetra Ashley

SUBSCRIBED AND SWORN TO BEFORE ME THIS

DAY OF _____, 20____.

Notary Public

Commission Expiration Date

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[agree - approval]

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Federal Rules of Civil Procedure

Rule 30

(e) Review By the Witness; Changes.

(1) Review; Statement of Changes. On request by the deponent or a party before the deposition is completed, the deponent must be allowed 30 days after being notified by the officer that the transcript or recording is available in which:

(A) to review the transcript or recording; and

(B) if there are changes in form or substance, to sign a statement listing the changes and the reasons for making them.

(2) Changes Indicated in the Officer's Certificate. The officer must note in the certificate prescribed by Rule 30(f)(1) whether a review was requested and, if so, must attach any changes the deponent makes during the 30-day period.

DISCLAIMER: THE FOREGOING FEDERAL PROCEDURE RULES ARE PROVIDED FOR INFORMATIONAL PURPOSES ONLY.

THE ABOVE RULES ARE CURRENT AS OF SEPTEMBER 1, 2016. PLEASE REFER TO THE APPLICABLE FEDERAL RULES OF CIVIL PROCEDURE FOR UP-TO-DATE INFORMATION.

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COMPANY CERTIFICATE AND DISCLOSURE STATEMENT

Veritext Legal Solutions represents that the foregoing transcript is a true, correct and complete transcript of the colloquies, questions and answers as submitted by the court reporter. Veritext Legal Solutions further represents that the attached exhibits, if any, are true, correct and complete documents as submitted by the court reporter and/or attorneys in relation to this deposition and that the documents were processed in accordance with our litigation support and production standards.

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